The United States Environmental Protection Agency: Use of Risk Assessment and Risk Management Methodologies

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I. Introduction

> ...[M]ake a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic health effects which may result from exposure to hazardous substances.[1]

This is the primary mission of the Risk Assessment and Management Commission (Risk Commission). The Clean Air Act Amendments of 1990 (CAAA),[2] created the Risk Commission reflecting Congress' concern over agency use of risk assessment and risk management techniques and methodologies to implement federal laws protective of human health.[3] The Risk Commission is to consider: methods for measuring and describing risks of chronic health effects from hazardous substances; methods to reflect uncertainties associated with estimation techniques, and whether it is possible or desirable to develop a consistent risk assessment methodology or a consistent standard of acceptable risk for various federal programs.[4]

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1. Pub. L. No. 101-549, Sec. 303(a), 104 Stat. 2574 (1990) (codified at 42 U.S.C.A. § 7412 note (West Supp. 1992)).

2. Pub. L. No. 101-549, 104 Stat. 2399 (1990) (codified at 42 U.S.C.A. §§ 7401-7671q (West Supp. 1992)).

3. *See* Clean Air Act Amendments of 1990 (CAAA), Pub. L. No. 101-549, Sec. 303, 104 Stat. 2399, 2574-2576 (codified at 42 U.S.C.A. § 7412 note (West Supp. 1992)).

4. The full charge to the Risk Commission is as follows:
> The Commission shall consider (1) . . . the use and limitations of risk assessment in establishing emission or effluent standards, ambient standards, exposure standards, acceptable concentration levels, tolerances or other environmental criteria for hazardous substances that present a risk

(continued...)

The Environmental Protection Agency (hereinafter the "Agency" or "EPA"), is one of several federal agencies which use risk assessment/risk management to implement laws protecting human health and the environment.[5] This paper examines EPA's use of risk analysis as a tool for setting the standards required by

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4. (...continued)
of carcinogenic effects or other chronic health effects and the suitability of risk assessment for such purposes; (2) the most appropriate methods for measuring and describing cancer risks or risks of other chronic health effects from exposure to hazardous substances considering such alternative approaches as the lifetime risk of cancer or other effects to the individual or individuals most exposed to emissions from a source or sources on both an actual and worst case basis, the range of such risks, the total number of health effects avoided by exposure reductions, effluent standards, ambient standards, exposure standards, acceptable concentration levels, tolerances and other environmental criteria, reductions in the number of persons exposed at various levels of risk, the incidence of cancer and other public health factors; (3) methods to reflects uncertainties in measurement and estimation techniques, the existence of synergistic or antagonistic effects among hazardous substances, the accuracy of extrapolating human risks from animal exposure data, and the existence of unquantified direct or indirect effects on human health in risk assessment studies; (4) risk management policy issues including the use of lifetime cancer risks to individuals most exposed, incidence of cancer, the cost and technological feasibility of exposure reduction measures and the use of site-specific actual exposure information in setting emissions standards and other limitations applicable to sources of exposure to hazardous substances; and (5) and comment on the degree to which it is possible and desirable to develop a consistent risk assessment methodology, or a consistent standard of acceptable risk, among various Federal programs. Sec. 303(b), 104 Stat. 2574-75. The membership of the Commission is bipartisan and is assured assistance from the executive branch. Sec. 303(c), (d), 104 Stat. 2575. The primary responsibility of the Commission is to produce a report to the Congress within four years of enactment containing the results of the Commission's investigation with "recommendations with respect to the appropriate use of risk assessment and risk management in Federal regulatory programs." Sec. 303(f), 104 Stat 2576.

5. *See infra* text accompanying notes 6-14.

law. First, the "command and control" statutory schemes created by Congress that have required agencies like EPA to use risk assessment and risk management will be reviewed. Some of the characteristics unique to environmental risks that prevent a traditional legal analysis of risk are then described along with the theoretical underpinnings for conservatism in risk assessment. Next, the development in EPA of risk assessment and risk management methodologies is discussed followed by an examination of the critiques that led to Congress establishing the Risk Commission. Finally, the judicial response to Agency use of risk assessment and risk management in support of agency rulemaking is surveyed.

II. Command and Control Regulation: The Role of Risk

Congress has given EPA responsibility for administering statutes[6] protecting surface water,[7] drinking water,[8] air[9] the ocean;[10] for managing chemicals,[11] pesticides,[12] and solid

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6. EPA also has responsibilities under the National Environmental Policy Act (NEPA), 42 U.S.C.A. §§ 4321-4370c (West Supp. 1992); and the Pollution Prevention Act of 1990, 42 U.S.C.A. §§ 13101-13109 (West Supp. 1992).

7. Federal Water Pollution Control Act (Clean Water Act), 33 U.S.C. §§ 1251-1387 (1988).

8. Safe Drinking Water Act, 42 U.S.C.A. §§ 300f-300j-26 (West Supp. 1992).

9. Clean Air Act, 42 U.S.C.A. §§ 7401-7671q (West Supp. 1992).

10. Marine Protection, Research, and Sanctuaries Act (Ocean Dumping Act), 33 U.S.C.A. §§ 1401-1445 (West Supp. 1992).

11. Toxic Substance Control Act (TSCA), U.S.C.A. §§ 2601-2671 (West Supp. 1992).

waste;[13] and for hazardous clean-up.[14] Generally, the statutes create standards that are achieved by "command and control" measures implemented by Agency regulations.[15] Command and control provisions can take several forms.

a. Congressional Action

Congress may act directly to ban or restrict an activity or substance. In the Toxic Substances Control Act (TSCA), Congress has banned the manufacture of any polychlorinated biphenyl (PCB).[16] Under the Clean Air Act, Congress banned the manufac-

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12. (...continued)
12. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C.A §§ 136-136y (West Supp. 1992). In addition, EPA sets tolerances for the residue of pesticides remaining on raw agricultural products and in processed foods under the Federal Food, Drug and Cosmetic Act (FFDCA). *See* 21 U.S.C.A. §§ 342, 346a, 348 (West Supp. 1992).

13. Resource, Conservation and Recovery Act (RCRA), 42 U.S.C.A. §§ 6901-6992k (West Supp. 1992).

14. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C.A. §§9601-9675 (West Supp. 1992).

15. Howard Latin, *Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and "Fine-Tuning" Regulatory Reforms*, 37 Stan. L. Rev. 1267 n.2 (1985): "The phrase 'command and control regulation' is used to describe 'measures that require or proscribe specific conduct by regulated firms.'" (citing Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 Calif. L. Rev. 1256, 1264 (1981)). One exception to the command and control model is found in the Clean Air Act Amendments of 1990, Title IV. Title IV establishes a sulfur dioxide allowance trading system based on a limited number of allowances; severe penalties are assessed for those who emit sulfur dioxide without having sufficient allowances. *See* Clean Air Act Amendments of 1990, Pub. L. No. 101-549, Title IV, 104 Stat. 2399, 2584 (1990) (codified at 42 U.S.C.A. §§ 7651-7651o (West Supp. 1992)).

16. 15 U.S.C. § 2605(e) (1988). 4

ture of chlorofluorocarbons (CFCs).[17] In the Ocean Dumping Act, Congress banned dumping sewage sludge and industrial wastes into ocean waters.[18] Under the Federal Food Drug and Cosmetic Act (FFDCA), Congress banned from use any food additive and, indirectly, certain pesticides remaining as residue in food, found to cause cancer in man or animal.[19] However, Congress typically does not use bans but delegates considerable discretion to the Agency to impose standards regulating substances or activities using rulemaking.

b. Technology-based standards

The command and control strategies available to EPA for imposing standards fall into three categories: technology-based standards, harm-based standards, and standards requiring individ-

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17. *See* 42 U.S.C.A Title VI (West Supp. 1992).

18. 33 U.S.C.A. § 1414b (West Supp. 1992).

19. 21 U.S.C.A. § 348(c)((3)(A) (West Supp. 1992). This provision is popularly known as the "Delaney Clause" and has been the cause of considerable contortions on the part of the Food and Drug Administration. *See* Richard A. Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 Yale J. on Reg. 1 (1988). Because pesticides which concentrate during processing from raw agricultural product to processed food have been held to be food additives, EPA must ban carcinogenic pesticides under the application of the Delaney Clause. U.S. v. Ewig Bros Co., Inc, 502 F.2d 715 (7th Cir. 1974).

EPA attempted to get around the absolute language of the Delaney Clause by allowing tolerances for pesticides posing only a "negligible human risk" of cancer (set at a lifetime risk of less than 1 in a million for a lifetime of exposure). *See* EPA, Regulation of Pesticides in Foods: Addressing the Delaney Paradox, 53 Fed. Reg. 41104 (1988). However, in Les v. Reilly, No. 91-70234, 1992 WL 153883 (9th Cir. Jul. 8, 1992), the court enforced a strict reading of the Delaney Clause and barred tolerances for even "negligible risk" pesticides.

ualized cost-benefit analysis ("balancing standards").[20] Technology-based standards require that the Agency determine what pollution control technologies are available to various industries, the amount of pollution control each provides, and the cost to implement each technology. Various statutes mandate that EPA require industry to use the "best available technology economically feasible (BAT)"[21] or "best available control technology (BACT)"[22] or other similar formulation to control emissions of pollutants. Technology-based standards do not address the remaining risk to human health or the environment posed by whatever level of pollutants escape the imposed technology. When creating technology-based standards, EPA must address various technological and economic uncertainties, but need not investigate risks posed by the pollutants that are regulated.[23]

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20. Howard Latin, *Regulatory Failure, Administrative Incentives, and the New Clean Air Act*, 21 Envtl. L. 1647, 1659-60 (1991). Professor Hornstein describes the three command and control models as: "environmental-quality-based" provisions that typically do not tolerate "any" significant risk to public health or welfare, technology-based provisions that do not tolerate risks which can "feasibly" be eliminated, and risk-benefit provisions that find intolerable those technologies, substances or processes that pose "unreasonable risk." Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 Colum. L. Rev. 562, 576 (1992).

21. 42 U.S.C.A. § 1311(b)(2)(A) (West Supp. 1992) (one of many technology based effluent limitation standards found in the Clean Water Act).

22. 42 U.S.C.A. § 7475(a) (West Supp. 1992) (one of many technology based air emission limitation standards found in the Clean Air Act).

23. Latin, *supra* note 20, at 1660.

c. Risk-based Standards

Unlike technology-based standards, harm-based standards and balancing standards require the Agency to determine the amount of risk to human health and/or the environment posed by various levels of a pollutant. When promulgating harm-based standards, EPA must determine what level of emissions is "acceptably safe" and then turn that finding into specific limits for each pollutant and each discharger. Before the CAAA of 1990, Section 112 of the Clean Air Act required that the Administrator of EPA must first establish the level of emission of any hazardous air pollutant at a level which provides an ample margin of safety to protect the public health.[24] This provision was held to require that EPA must determine the emission standard on the basis of safety without considering costs of control or whether such technology was feasible; only then may the Agency consider technology-based options to make the standard more protective.[25] Because any exposure to a carcinogen is thought by scientists to create some probability of cancer, finding an ample margin of safety for carcinogenic hazardous air pollutants would require a

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24. 42 U.S.C. § 7412(b)(1)(B) (1988). The 1990 Clean Air Act Amendments changed § 112 to require the Administrator to create technology based standards for 189 hazardous air pollutants (as set out in the Amendments by Congress) based on the Maximum Available Control Technology (MACT). Clean Air Act Amendments of 1990, Pub. L. No. 101-549, sec. 301, § 112, 104 Stat. 2399, 2531-2574 (1990) (codified at 42 U.S.C.A. § 7412 (West Supp. 1992)). *See infra* text accompanying notes 41-47.

25. National Resources Defense Council v. EPA, 824 F.2d 1146 (D.C. Cir. 1987).

ban of all emissions.[26] The difficulty of reconciling zero risk with the importance to our society of the processes giving rise to hazardous air pollutants was one reason EPA regulated only seven chemicals in 18 years.[27]

Another example of a harm-based standard is found in Section 307 of the Clean Water Act of 1972 which directs the Agency to identify toxic water pollutants and set toxic effluent standards such that: "Any effluent standard (or prohibition) promulgated under this section shall be at that level which the Administrator determines provides an ample margin of safety."[28] EPA encountered similar difficulties here and set only six standards by 1976 resulting in a number of lawsuits by environmental groups.[29] Ultimately the Agency entered into consent decrees under which it was to promulgate standards using technology-based standards instead of harm-based standards.[30]

Balancing standards also require the Agency to determine the amount of risk to human health and/or the environment posed by various levels of a pollutant. However, once the risk is quantified at likely exposure levels, EPA must balance the risk levels

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26. *See* Clean Air Act Amendments of 1989, S. Rep. No. 228, 101st Cong., 1st Sess. 128 (1989).

27. *Id.*

28. Pub. L. 92-500, Sec. 2, § 307(a)(4), 86 Stat. 856 (1972) (codified at 33 U.S.C. § 1317(a)(4) (1988).

29. *See* National Resources Defense Council v. Train, 519 F.2d 287 (D.C. Cir. 1975).

30. *See* Sheldon M. Novick, et. al., 2 Law of Environmental Protection § 12.05(3)(a)(iii)(E) (1987 & Supp. 1992).

with control costs, indirect economic effects, possible social dislocation, and other relevant concerns to select the standard for each regulated substance.[31] EPA must examine the potential benefits of alternative methods of control, the costs of alternative control measures, and then assess whether the overall benefits justify the economic and social costs of regulation when balanced against the amount of risk. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and TSCA require the Agency to create and apply balancing standards.

Under FIFRA, new pesticides that the Agency determines pose unreasonable risk to man or the environment are denied registration; existing pesticides with registrations may also be reviewed and if the Agency determines they pose unreasonable risk the registrations are cancelled.[32] Under TSCA, EPA may ban chemical substances that "present or will present an unreasonable risk of injury to health or the environment," but only after considering several measures of control short of an outright ban.[33] The key under both statutes is the word "unreasonable." Unlike the harm-based standards in which no probability of harm is permitted, FIFRA and TSCA recognize that some risk might be worth the

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31. Latin, *supra* note 20 at 1659-60.

32. 7 U.S.C. §§ 136a, 136d (1988). *See e.g.* EPA, Notice of Intent, 39 Fed. Reg. 11,298 (1974) (notice of intent to cancel most of chlordane's uses).

33. 15 U.S.C. § 2605(a) (1988). EPA's attempt to ban most uses of asbestos was remanded back to the Agency by the court in Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991). *See infra* text accompanying notes 295-307.

benefit offered by the use of a chemical substance. In the case of pesticides, FIFRA looks at the risk posed by a particular pesticide in relation to, among other things, the increased yield of food through elimination of the insects it controls and whether there are reasonable substitutes to using that particular pesticide.[34]

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34. *See* U.S. Gen. Acct. Office, Rep. to the Subcomm. on Health and Environment, House Comm. on Energy and Commerce: Pesticides—EPA's Use of Benefit Assessments in Regulating Pesticides 11 (1991). EPA incorporates biological and economic factors into its pesticide benefits analysis:

> EPA's guidance for the biological section of its pesticide benefit analyses calls for the agency to examine and summarize control methods that are recommended by pest management authorities and professionals and are actually used to control the pest(s) for which the review chemical is registered. Alternatives to be considered include other chemicals, integrated pest management (PM) practices, and nonchemical concepts, such as ridge tilling, that are likely to be available for future use. Comparative evaluations of the performance of alternatives, chemical and nonchemical, are to be made, both in terms of pest control efficacy and of crop yield/quality over a range of both pest infestation and pesticide application levels. The guidance calls for attention to situations for which no alternative control method is available, to problems with pests developing resistance to pesticides, and to differences arising from the influences of geography, weather, timing, and pest population dynamics. Guidelines for the economic analysis part of EPA's pesticide benefit analyses direct the agency to estimate dollar values for differences in crop yield and quality identified in the biological analysis. In so doing, economists are instructed to estimate impacts on users, distributors, and consumers.
>
> EPA uses two primary methodologies to formally estimate the economic benefits of pesticides: partial budgeting and agricultural modeling. EPA applies formal pesticide benefit assessment methods principally during special review. EPA's main objective is to determine the dollar value of biological differences between pesticides, i.e., to measure the value of the variation in crop yields and quality attributable to the pesticides in special review and to selected alternatives.

(continued...)

As with harm-based standards, EPA has had difficulty implementing balancing standards. Since the enactment of TSCA, EPA has imposed restrictive regulation on only five existing chemical substances.[35] Under FIFRA, EPA came under intense criticism for its slowness in updating the registrations of older pesticides that have not undergone modern testing and evaluation under new guidelines for risk assessment.[36] The Agency's inability to regulate toxic chemicals within a reasonable time frame undoubtedly is one reason Congress created the Risk Commission.[37]

d. Mixed Standards

Newer statutes use a combination of the command and control strategies. Under the Safe Drinking Water Act Amendments of 1986, EPA first sets a harm-based standard—the maximum contaminant level goal—at which "no known or anticipated adverse effects on the health of persons occur and which allows an

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34. (...continued)
Id. See also U.S. Gen. Acct. Office, Rep. to the Subcomm. on Health and Environment, House Comm. on Energy and Commerce: Pesticides—Better Data Can Improve the Usefulness of EPA's Benefit Assessments (1991).

35. Alison C. Flournoy, *Legislating Inaction: Asking the Wrong Questions in Protective Environmental Decisionmaking*, 15 Harv. Envtl. L. Rev. 327, 330 (1991) (citing General Accounting Office, Toxic Substances: Effectiveness of Unreasonable Risk Standards Unclear 1-2 (1990).

36. See Scott Ferguson and Ed Gray, *1988 FIFRA Amendments: A Major Step in Pesticide Regulation*, 19 Envtl. L. Rep. (Envtl. L. Inst.) 10070 (1989).

37. *See* Flournoy, *supra* note 37, at 330.

adequate margin of safety."[38] Then, the Agency creates national primary drinking water regulations for contaminants for which goals have been set by specifying maximum levels for such contaminants which are as close to the maximum contaminant level goals as is feasible.[39] Feasibility is defined in terms of technology-based standards with reference to the best technology available.[40] Under the CAAA of 1990, hazardous air pollutant emitters are first subject to a technology-based standard—Maximum Achievable Control Technology (MACT).[41] Congress recognized though, that MACT might not reduce emissions sufficiently to remove all risks to human health and the environment; there might remain "residual risk."[42] Accordingly, Congress requires EPA, after six years of the passage of the CAAA of 1990, to investigate and report back to Congress the risk remaining to public health from whatever level of pollutants escape MACT into the environment.[43]

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38. Pub. L. 99-339, 100 Stat 642 (codified at 42 U.S.C.A. § 300g-1(b)(4) (West Supp. 1992)).

39. *Id.*

40. 42 U.S.C.A. § 300g-1(b)(5) (West Supp. 1992).

41. Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399, 2539-40 (1990) (codified at 42 U.S.C.A. §§ 7412(d)-(West Supp. 1992)).

42. Clean Air Act Amendments of 1989, S. Rep. No. 228, 101st Cong., 1st Sess. 148 (1989).

43. Clean Air Act Amendments of 1990, Pub. L. No. 101-549, 104 Stat. 2399, 2543-44 (1990) (codified at 42 U.S.C.A. §§ 7412(f)(1) (West Supp. 1992)). In addition to reporting on the residual risk, Congress also requires EPA to report on "the methods of calculating risk," "the significance of any remaining risk" and "any uncertainties in risk assessment methodology or other health assessment technique." *Id.*

Unless Congress acts upon the report by enacting legislation within eight years of the passage of the CAAA of 1990, EPA must, if necessary, promulgate stricter harm-based standards with an adequate margin of safety to protect public health from residual risk.[44] For carcinogens, Congress directs EPA to create more protective harm-based standards for all sources which emit a pollutant where MACT does not limit lifetime excess cancer risks to the individual most exposed to less than one in one million.[45] This approach returns to the first step of the two step test set out in *National Resources Defense Council v. Environmental Protection Agency*[46] where EPA must first determine a safe or acceptable level of risk without considering cost or feasibility of control.[47]

e. Other Regulatory Decisions

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44. 42 U.S.C.A. § 7412(f)(2)(A) (West Supp. 1992). Congress also directs the Agency to create standards to protect against adverse environmental effects caused by the residual risk of hazardous air pollutants, but the Administrator must consider costs, energy, safety, and "other relevant factors" before doing so. *Id.* Because Congress failed to address how the Administrator should weigh these factors against adverse environmental consequences, we will have to wait ten or so years to see how courts assist in this endeavor.

45. 42 U.S.C.A. 7412(f)(2)(A) (West Supp. 1992). The one in a million risk standard acts only as a screen for deciding when to impose more protective harm-based standards with an adequate margin of safety. The language used in the Senate Report required that emitters need only achieve the one in a million cancer risk standard if MACT did not achieve that level of safety. However, that language was dropped in the enacted legislation. *See* Clean Air Act Amendments of 1989, S. Rep. No. 228, 101st Cong., 1st Sess. 148, 523 (1989).

46. 824 F.2d 1146 (D.C. Cir. 1987).

47. *See supra* text accompanying notes 24-27.

In addition to setting standards for pollution limitation, the Agency also uses risk assessment/ risk management to make other decisions. In those instances where the Agency has discretion to prioritize its regulatory agenda, the Agency attempts to apply Agency resources to those problems posing the greatest risk first (worst-first analysis).[48] Other statutory provisions require that EPA determine a substance or activity pose a particular level of risk before EPA may add that activity to a list subject to various regulations or requirements. Under RCRA, Congress requires comprehensive "cradle to grave" regulation of hazardous waste.[49] Because of the cost of compliance, the stakes are high when EPA determines whether a particular waste is hazardous.[50] EPA "lists" wastes as hazardous based on the presence of hazard characteristics, toxicity or acute toxicity.[51] Under CERCLA, Congress imposes liability for the clean-up of waste sites. The stakes are equally high as EPA assesses risk to

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48. *See* Hornstein, *supra* note 20 at 567-69 (setting out several examples of statutory provisions giving EPA authority to make risk-based comparisons.)

49. The Resource, Conservation and Recovery Act of 1976 ("RCRA"), Public L. No. 94-580, 90 Stat. 2798 (1976) amended the 1965 Solid Waste Disposal Act, Pub. L. No. 89-272, 79 Stat. 989. Subtitle C of RCRA sets out the requirements for managing hazardous waste. The entire Solid Waste Disposal Act, as amended through 1991 is codified at 42 U.S.C.A. §§ 6901-6992k (West Supp. 1992).

50. *See* Randolph L. Hill, *An Overview of RCRA: The "Mind-Numbing" Provisions of the Most Complicated Environmental Statute*, 21 Envtl. L. Rep. (Envtl. L. Inst.) 10254, 10260 (May 1991) .

51. *See* 40 C.F.R. § 261.3 (1991).

place sites on the National Priority List for clean-up,[52] to determine which substances are subject to clean-up,[53] and to determine how clean a site must be after clean-up.[54]

III. The Nature of Environmental Risk

Because of the many decisions EPA must make which are based on risk, the Agency has had to confront several analytical difficulties presented by the nature of environmental risk. At the outset, the terms risk and uncertainty need to be defined. Risk is generally understood to be the measure of the probability and the severity of a loss; uncertainty refers to a lack of definite knowledge.[55] Risk can be expressed with certainty if the mechanism of a process is known with precision, e.g., the toss of a coin.[56] The determination of risk from environmental problems is plagued by uncertainty. Many gaps of knowledge must be bridged before a risk estimate may be given for a particular environmental risk. Controversy over how these gaps are bridged

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52. 42 U.S.C. § 9605(a)(8) (1988).

53. 42 U.S.C. §§ 9601(14), 9602 (1988).

54. 42 U.S.C. § 9621(b)(1) (1988). EPA has published extensive risk assessment guidance for making risk based determinations under CERCLA. *See* EPA, Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Interim Final) (1989); EPA, Risk Assessment Guidance for Superfund Volume II Environmental Evaluation Manual (Interim Final) (1989); EPA, Exposure Factors Handbook (1989); and EPA, Guidance for Data Useability in Risk Assessment (Interim Final) (1989).

55. Chris G. Whipple, *Dealing with Uncertainty About Risk in Risk Management* in National Academy of Engineering, Hazards, Technology and Fairness 46 (1985).

56. *Id.*

by agencies and the impact these decisions make on the resulting risk estimates is among the reasons why Congress asked the Risk Commission to investigate methods to reflect the uncertainty inherent in the risk assessment process.[57]

The nature of environmental risk and its susceptibility to legal analysis has been the topic of many commentators.[58] Some[59] begin by comparing environmental risk to a standard familiar to every first year law student—the B ~ PL negligence formula which Judge Learned Hand used to describe the extent of a barge owner's duty to provide against injuries caused when a

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57. *See supra* note 4.

58. *See e.g.* Hornstein, *supra* note 20; Flournoy, *supra* note 35; Howard Latin, *The "Significance" of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty*, 10 Ecology L.Q. 339 (1982); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 Yale J. on Reg. 89 (1988); John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy and Toxic Substances Control*, 91 Colum. L. Rev. 262 (1991); Dennis J. Paustenbach, *Health Risk Assessment: Opportunities and Pitfalls*, 14 Colum. J. Envtl. L. 379 (1989); Adam M. Finkel, *Is Risk Assessment Really Too Conservative?: Revising the Revisionists*, 14 Colum. J. Envtl. L. 427 (1989).

59. *See e.g.*, Hornstein, supra note 20 at 571 ("This conceptual formulation of risk is familiar to lawyers through such well known applications as Learned Hand's "formula" for risk in the law of negligence."); Robert F. Blomquist, *The Science Advisory Board's Report on "Reducing Risk": Some Overarching Observations Regarding the Public Interest*, 22 Envtl. L. 149, 152 (1991) (quoting United States v. Carroll Towing Co., 159 F.2d 169 (2nd Cir. 1947)); Francesco Parisi & Paolo F. Ricci, Book Review, 18 Ecology L. Q. 459, 475 (1991)(reviewing Norman J. Vig & Michael E. Craft (eds.), Environmental Policy in the 1990s (1990))(noting the resemblance between Learned Hand's negligence formula and the balancing required by "unreasonable risk" standard statutes such as FIFRA and TSCA).

barge breaks free from its mooring.[60] Judge Hand defined his formula as follows: (1) P—the probability of an event occurring, (2) L—the gravity of the harm caused if the event occurs (loss), and (3) B—the burden of adequate precautions against the event occurring.[61] Other commentators consider the utility (U) or value of the interest an actor is trying to advance creating the modified formula BU ~ PL.[62] Using this formula or a similar variation countless attorneys have asked innumerable juries to determine whether an actor's actions presented an unreasonable risk.[63]

At first glance, one might suspect that setting harm-based and balancing environmental standards would be no more difficult than determining negligence. For example, we can examine a chemical that might cause cancer; cancer becomes the loss (L) and we determine the probability of the cancer occurring (P) versus the burden of life without the chemical (or of life with varying restrictions placed on the use of the chemical) and whatever benefits the unrestricted use of the chemical would confer. This

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60. United States v. Carroll Towing Co., 159 F.2d 169 (2nd Cir. 1947).

61. *Id.* at 173.

62. *See* W. Page Keeton et. al., Prosser & Keeton on the Law of Torts § 31 (5th ed. (1984)) ("[T]he standard of conduct [for negligence] is usually determined upon a risk-benefit form of analysis: by balancing the risk, in the light of the social value of the interest threatened, and the probability and extent of the harm, against the value of the interest which the actor is seeking to protect, and the expedience of the course pursued.")

63. *Id.*

is an approximation of what must be done to set a balancing standard.[64]

a. The Case for Conservatism

Despite the familiarity lawyers and judges have acquired using the negligence risk-benefit framework for resolving disputes, the nature of environmental risks has not lent itself to this simple analysis. Professor Talbot Page in his seminal article, *A Generic View of Toxic Chemicals and Similar Risks*, highlighted several important bases upon which one can distinguish environmental risks from other risks which complicate the BU ~ PL analysis.[65] Professor Page uses characteristics to describe environmental risk which he divided into two groups. The first group of characteristics emphasize the uncertain nature of environmental risk—ignorance of mechanism, modest benefits, catastrophic costs, and low probability of catastrophe (rarity of effect).[66] The second group—internal benefits, external costs, collective risks, latency and irreversibility of effect impact upon the ability of an agency like EPA to manage these risks.[67] To illustrate how these characteristics may be used to describe risks, we can compare the traditional risk posed by a barge that might break loose with the environmental risk posed by

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64. *See supra* text accompanying notes 31-34.

65. Talbot Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 Ecology L. Q. 207 (1978).

66. *Id.* at 208-211.

67. *Id.* at 212-14.

a pesticide with the potential for widespread human exposure that might cause cancer.

The mechanism by which a barge would break loose is known to a great extent—ropes wear thin and break if not properly maintained; careless or improperly trained deckhands may not tie a barge off properly; or a barge may be improperly placed where it can be struck by another ship causing it to break free. In contrast, the mechanisms by which cancers (and other chronic health effects) are caused are still largely unknown. Even after years of study our knowledge of cancer is still woefully incomplete; how any particular substance causes cancer at the cellular level remains largely a mystery.[68] The second characteristic looks at the potential for catastrophic costs. While a runaway barge has the potential for property damage and personal injury, the total damage is small and geographically localized relative to the loss of human life, increased medical costs and human suffering associated with widespread exposure to a carcinogen. His third characteristic examines the magnitude of the benefit associated with the risk. The importance of using barges in commerce relative to the potential harm strikes one as reasonable when compared to the risks associated with other forms of transportation or to life without such transportation. In contrast, careful evaluation of the benefits of a larger food supply must be made against an increase risk of cancer. With the availabili-

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68. Frank B. Cross, Environmentally Induced Cancer and the Law: Risks, Regulation, and Victim Compensation 10 (1989) [hereinafter Cross, Cancer and the Law].

ty of alternative pesticides or nonchemical pest controls or deciding to live with less of a particular food, the benefits can appear relatively small. The fourth characteristic examines whether the risk has a low subjective probability. Barges probably break free with some degree of frequency. Under the Clean Air Act, Congress requires increased regulation of substances found to cause cancer in as few as one in a million persons over a lifetime of exposure.[69] For runaway barges, the mechanisms by which they may cause harm and the benefits, costs, and probability of catastrophe from their use may largely be learned or understood by viewing the past use of barges and the historical occurrences of accidents. For toxic chemicals and other environmental risks, we usually have no historical data upon which to draw such conclusions and must rely on surrogates such as studies with animals.[70] Risk assessment methodologies must "fill in the blanks" to provide a basis for assessing risk in the absence of direct, historical evidence.

Turning to the second group of characteristics, the fifth characteristic examines the internal transfer of benefits associated with the risks. For a pesticide any benefit from producing a larger crop gets transferred through the market and is reflected in the price a company is able to get for its product. This is the same for our runaway barge. When looking at the transfer of costs (the sixth characteristic), the transfer of costs of a

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69. *See supra* text accompanying note 45.

70. *See infra* text accompanying notes 180-190.

runaway barge are internal as well. Damage caused by the barge attributed to the owner will be paid by the owner either in direct damages or through insurance premiums. However, the initial costs associated with a carcinogen and other environmental risks are transferred externally because a person with cancer, in most cases, cannot trace the cause of his illness and must pay any associated health and loss of longevity costs himself.[71] Until the risk from the chemical is described with some certainty, costs are not reflected in the market price.[72] The seventh characteristic, collective risk, describes a risk that is borne by many people simultaneously. The widespread exposure to a potentially carcinogenic chemical is far greater than the relatively localized and certain path of exposure to a runaway barge along a waterway. The eighth characteristic, latency is the amount of delay between the initiation of a hazard and its manifestation of effect.[73] The time between a barge breaking away and the manifestation of the eventual harm is likely to be a matter of minutes or possibly seconds. Carcino-

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71. Some cancers fall within the set of "signature diseases" so called because a specific substance has been proven to cause a specific disease. *See* Arnold W. Reitze, *A Century of Air Pollution Control Law: What's Worked; What's Failed; What Might Work,* 21 Envtl. L. 1549, 1567 n. 103 (1991) (giving as examples: byssinosis—cotton dust; mesothelioma and asbestosis—asbestos; coal workers' pneumoconiosis—coal dust; lead poisoning and other diseases from heavy metal exposure).

72. Some examples of substances whose costs were not reflected in the original market price include: asbestos, tris (once used as a flame retardant in children's clothing), Agent Orange, dalkon shields.

73. Page, *supra* note 65, at 213.

gens may take a lifetime to result in a malignant tumor. Long latencies combined with ignorance of mechanism increase the possibility that the cause may be masked by other confounding factors such as a lifetime of smoking or poor diet. The ninth characteristic is the extent to which the adverse effect may be reversed. A runaway barge may be captured by tugs if discovered in time. The most likely damage, property damage, could in most cases easily be repaired. The release of carcinogens, however, cannot easily be reversed. Measurable amounts of DDT are still reported in wild life despite the ban of almost all uses of the substance in 1972.[74] In addition, while recovery rates for cancer patients have increased, cancer, once initiated, is decidedly not easily reversed. Professor Page highlights the last two characteristics, latency and irreversibility, as having profound ethical and institutional implications because they raise questions concerning fair distributions of risk over time and how institutions can be designed to anticipate adverse effects rather than merely react to existing known effects.[75]

Professor Page distinguished environmental risks from what he called "classical pollution;" characterized as less serious, yet more visible because classical pollution generally causes acute effects in the short term that are more easily remedied by

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74. Opinion and Order of the Administrator, I.F. & R. Dockets No. 63, Consolidated DDT Hearings, June 30, 1972.

75. Page, *supra* note 65, at 214.

readily available methods.[76] He also advanced the idea of false positives and false negatives to show how to consider environmental risk despite its attendant uncertainties.[77]

In any test to determine whether a hypothesis is true, two types of error may occur. Either, you receive a false negative, i.e., the test indicates the hypothesis is false when it is true, or, second, you receive a false positive, i.e., the test indicates the hypothesis is true when it is false. In a criminal trial, the burden of proof is constructed to minimize the possibility of a false positive, i.e., a verdict finding an innocent man guilty. The bias reflects society's belief that it is better to err in allowing a guilty man to go free (a false negative). When testing a potentially toxic chemical, test findings may indicate a toxic chemical is not toxic (a false negative) or a nontoxic chemical is toxic (a false positive). Because of the characteristics of environmental risk, in particular latency, irreversibility and catastrophic costs, the cost of a false negative is usually much higher than the cost of a false positive.[78] But attempting to prove that a nontoxic chemical is nontoxic is attempting to prove a negative and introduces what

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76. *Id.* at 217. His examples for classical water pollutants include suspended solids, biological oxygen demanding wastes, eutrophicants and detergents; and for classical air pollutants he includes the criteria air pollutants. *Id.* at 218.

77. *Id.*

78. *Id.*

Professor Page calls the fallacy of the false negative.[79] Using an example of a pail filled with white tennis balls, he asked how can one determine the possibility that the pail also contains a single yellow tennis ball if one can only look at the top layer? The answer depends on how many layers of white tennis balls exist in the pail. If the pail contains more than one layer there will always be the possibility of a false negative. One must then look at the structure of the problem and attempt to obtain more information. If we can learn with certainty the number of layers we can be certain of the probability of a false negative.

Knowledge gaps like the mechanisms of cancer, must wait for scientific breakthroughs to gain insight into the "pail" and to create models with reliable predictive power; otherwise the power of what we learn from tests producing negative results is limited. Information gaps, on the other hand, may be filled by applying techniques from the existing science base.[80]

Professor Page proposed comparing the cost of a false negative weighted by its probability with the cost of a false positive weighted by its probability; the choice with the lowest cost becomes the basis for a regulatory decision.[81] He acknowledged the difficulties of determining the probabilities and

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79. *Id.* at 216.

80. *See* Lakshman Guruswamy, *Integrating Thoughtways: Reopening of the Environmental Mind?*, 1989 Wisc. L. Rev. 463 notes 199 and 200 (distinguishing making decisions with data uncertainty versus indeterminacy which arises out of attempts to ask questions to which there are presently no answers.)

81. Page, *supra* note 65, at 236-37.

proposed that because of the perceived high costs of an environmental false negative (e.g. widespread cancer), a substance or activity be considered hazardous if there is at least a reasonable doubt. This argument for conservatism has had great force in the development of the environmental risk assessment methodologies.

b. The Limits of Conservatism

But Dr. Chris Whipple has shown that such analytical conservatism makes sense only if three assumptions are true:

> (1) that the disparity in social costs between false negatives and false positives is great;
> (2) that risk management decisions are insensitive to resource constraints and do not incur significant opportunity costs; and
> (3) that activities or agents identified as hazardous (whether true positives or false positives) can be eliminated without the creation of significant new risks.[82]

If these assumptions are not true, it may well be that conservative choices used in risk assessment methodologies will not be protective. If risk assessors and managers do not examine these assumptions, the use of the most conservative options may create only the perception of greater protection.

The legal remedy available to individuals for exposure to environmental risk—the toxic tort—has been largely unsatisfactory because of the difficulty of proving causation; courts have been unsympathetic to suggestions that they base liability on probabi-

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82. Whipple, *supra* note 55, at 48-49.

listic causation or that they apportion damages.[83] Latency, low probability of catastrophe (rarity of effect) and the presence of confounding factors (due to unknown mechanism of effect) have prevented courts from finding liability; plaintiffs are unable to meet the more likely than not burden of proof.[84] Professor Applegate concludes that the failure of tort law to internalize costs (as Professor Page suggested) and to act as a deterrent to environmental risk creation, became an important motivation for government regulation.[85]

Unconstrained by traditional tort principles[86] and faced with statutory mandates to develop risk based standards, agencies have made full use of risk assessment methodologies. William Ruckelshaus, former Administrator of EPA described the importance of risk assessment:

> There appears to be no substitute for risk assessment, in that some sort of risk finding is what tells us that there is any basis for regulatory action in the first place. The alternative to not performing risk assessment is to adopt a policy of either reducing all potentially toxic emissions to the greatest degree technology allows or banning all substances for which there is any evidence of harmful effect, a policy that no technological society could long survive. Beyond that, risk assessment is an irreplaceable tool for setting priorities among the tens of thousands of substances that could be subjects of control actions—substances that

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83. *See* Applegate, *supra* note 58, at 272 n. 59 (collecting cases denying recovery for future toxic harm).

84. *Id.* at 272.

85. *Id. See also* Reitze, *supra* note 71 at 1567-68 (concluding that the tort system fails to adequately compensate for injuries caused by exposure to toxic air pollutants).

86. *See supra* text accompanying notes 269-272.

vary enormously in their apparent potential for causing disease.[87]

IV. The Risk Assessment - Risk Management Framework

Federal agencies were greatly influenced by the recommendations in a committee report of the National Research Council (NRC) in 1983 on risk assessment in the federal government.[88] The NRC examined the practice of risk assessment and risk management by the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the Consumer Product Safety Commission (CPSC) and the EPA.[89] The basic framework described by the NRC is still used by the EPA for risk assessment and risk management of human health risks[90] although the risk assessment and risk management framework for estimating risks from hazardous substances to ecosystems is still in the process

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87. William D. Ruckelshaus, *Risk, Science, and Democracy*, 1 Issues in Science and Technology 19 (1985) reprinted in Readings in Risk 105 (Theodore S. Glickman & Michael Gough eds.) (1990).

88. National Research Council, Risk Assessment in the Federal Government: Managing the Process (1983) [hereinafter Managing the Process]. The Food and Drug Administration contracted with the National Academy of Sciences to conduct a study into risk assessment in response to a directive from Congress. *Id.* at iii.

89. *Id.* at 40-42.

90. *See* Memorandum from F. Henry Habicht II, Deputy Administrator of EPA, *Guidance on Risk Characterization for Risk Managers and Risk Assessors to Assistant and Regional Administrators* (Feb. 26, 1992) (available from BNA) [hereinafter Habicht Memo]. The Habicht Memo contained as an attachment U.S. EPA, Risk Assessment Council, *Guidance for Risk Assessment* (Nov. 1991) [hereinafter RAC Guidance].

of development.[91] Although Congress did not direct the Risk Commission to examine risk assessment practices with regard to ecosystems,[92] the Agency has tremendous responsibilities for performing ecosystem risk assessments under the environmental statutes.[93]

The basic framework begins with the definitions of risk assessment and risk management. Risk assessment is defined to mean the characterization of the potential adverse effects from exposure to environmental hazards.[94] Risk management is the process used by risk managers who consider the result of the risk assessment as one set of information to be considered with political, social, economic and engineering information when evaluating alternative regulatory actions.[95] In EPA, risk assessment is performed by scientists, statisticians and analysts

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91. Recent efforts by the Agency in the development of ecosystem risk assessment are described in EPA, Peer Review Workshop Report on a Framework for Ecological Risk Assessment (1992); EPA, Report on the Ecological Risk Assessment Guidelines Strategic Planning Workshop (1992); EPA, Framework for Ecological Risk Assessment (1992).

92. *See* Charge to the Commission *supra* note 4.

93. In 1988, a subcommittee of the EPA Science Advisory board identified 39 statutory provisions requiring EPA to accomplish ecological risk assessments and 18 statutory provisions implicitly authorizing EPA to accomplish an ecological risk assessments. Subcomm. on Ecological Effects, Science Advisory Bd., U.S. EPA, Report of the Subcommittee on Ecological Effects: Strategies for Ecological Effects Research (1988) (attached as Appendix E to Science Advisory Bd., U.S. EPA, Future Risk: Research Strategies for the 1990s (1988))

94. Managing the Process, *supra* note 88, at 18.

95. *Id.* at 14-15.

who work in the Office of Research and Development, Office of Pesticides and Toxic Substances, the Carcinogen Risk Assessment Verification Endeavor and other science-oriented offices.[96] Risk management is performed by Agency managers and decision-makers for whom the end result is often the promulgation of a successful regulation setting a harm-based or balancing standard.[97]

a. Risk Assessment

Risk assessment is divided into four steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization.[98] NRC defined hazard identification as the process of determining whether exposure to an agent can cause an increase in the incidence of any health condition and requires an assessment of the nature and strength of the evidence of causation.[99] EPA has defined hazard identification in the form of a question: "What do we know about the capacity of an environmental agent for causing cancer (or other adverse effects) in laboratory animals and in humans?"[100] Congress has used various formula-

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96. *See* RAC Guidance, *supra* note 90, at 2-3.

97. *Id.* at 3.

98. Managing the Process, *supra* note 88. *See also* William W. Lowrance, Of Acceptable Risk 18 (1976)(identifying similar four step process as four lines of investigation into risk: (1) Define the conditions of exposure [exposure assessment], (2) Identify the adverse effects [hazard identification], (3) relate exposure with effect [dose-response], (4) estimate overall risk [risk characterization]); Quantitative Risk Assessment in Regulation (Lester B. Lave, ed.)(1982).

99. *Id.* at 19.

100. RAC Guidance, *supra* note 90, at 11.

tions to describe the hazards EPA must regulate. For example, under the Clean Air Act Amendments of 1990, EPA must add pollutants to a hazardous air pollutant list which may present a "threat of adverse human health effects (including substances... which may reasonably be anticipated to be carcinogenic, mutagenic, teratogenic, neurotoxic [or] which cause reproductive dysfunction, or which are acutely or chronically toxic)."[101] Under the Clean Water Act, EPA must select water pollutants for a toxic pollutant list after "taking account the toxicity of the pollutant."[102] The decision of which adverse health impact end point to choose when engaging in risk assessment is significant. If a substance is both carcinogenic and toxic in some other way, the Agency could look to cancer as being the most sensitive end point, because the levels at which a substance is actively carcinogenic is assumed to have no threshold.[103] Recent research has doubt upon this assumption because dioxin's greatest threat at low exposure levels seems to be to the human immune system instead of causing cancer.[104]

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101. 42 U.S.C.A. § 7412(b)(2) (West Supp. 1992). One must question whether Congress intended that EPA have direct proof that a substance cause reproductive dysfunction while needing only to find that a substance is reasonably anticipated to be carcinogenic before adding such substances to the list.

102. 33 U.S.C.A § 1317(a)(1)(West Supp. 1991).

103. supra back to Congressional report.

104. *See* Karen F. Schmidt, *Dioxin's Other Face: Portrait of an Environmental Hormone*, 141 Science News 24 (Jan. 11, 1992).

NRC defined dose-response assessment as the process of characterizing the relation between the dose of a potentially hazardous agent taken or received and the incidence of an adverse health effect in exposed populations and then estimating the probability of effect as a function of human exposure to the agent.[105] EPA asks "What do we know about the biological mechanisms and dose-response relationships underlying any effects observed in the laboratory or in epidemiological studies providing data for the assessment?"[106] The dose-response assessment step of the risk assessment process received widespread attention during the public debate over assessing the risk posed by the artificial sweetener saccharin because of the extrapolation from animal studies to humans and the extrapolation from the high doses the animals received to the lower doses humans typically receive.[107]

The third step, exposure assessment, is defined by NRC as the process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent already present in the environment or of estimating hypothetical exposures from the release of new agents into the environment.[108] Again, EPA de-

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105. Managing the Process, *supra* note 88, at 19.

106. RAC Guidance, *supra* note 90, at 12.

107. *See* Saccharin Ban Moratorium, H.R. Rep. No. 658, 95th Cong., 1st Sess. (1977) (discussing the reliance of the FDA on Canadian animal studies to extrapolate to human levels of consumption in which the animals were fed saccharin at levels as high as five percent of their daily total diet).

108. Managing the Process, *supra* note 88, at 20.

fines exposure assessment in the form of a question: "What do we know about the paths, patterns, and magnitudes of human exposure and numbers of persons likely to be exposed?"[109] Real world exposure is necessary to create a risk of harm because even the most toxic of chemicals cannot cause harm without ingestion, inhalation or contact with a human body.[110]

The final step, risk characterization, is the process of estimating the incidence of the hazard under the various conditions of human exposure described in the exposure assessment.[111] In the parlance of EPA, the question becomes: "What do other assessors, decisionmakers, and the public need to know about the primary conclusions and assumptions, and about the balance between confidence and uncertainty in the assessment?"[112] The Agency question seems more complete because of the Agency's recent emphasis on ensuring risk assessors provide risk managers complete information. The Deputy Administrator was concerned

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109. RAC Guidance, *supra* note 90, at 13.

110. This issue was discussed in Chemical Manufacturers Ass'n v. EPA, 859 F.2d 977 (D.C. Cir. 1988) where the court was asked to determine when EPA can require testing of existing chemicals under TSCA. Before EPA can promulgate a test rule TSCA requires that EPA must find that a substance "may pose an unreasonable risk of injury to health." *Id.* (citing 15 U.S.C. § 2603(a)-(1)(A)(i)(1988)). An issue before the court was whether EPA need produce direct evidence of exposure. While accepting that exposure is a necessary component of "unreasonable risk," the court held that direct evidence was not necessary so long as there existed a more-than-theoretical basis for inferring the existence of exposure. *Id.* at 989. *See also* Ausimont U.S.A., Inc. v. EPA, 838 F.2d 93 (3rd Cir. 1988).

111. Managing the Process, *supra* note 88, at 20.

112. RAC Guidance, *supra* note 90, at 14.

that EPA risk assessors in performing risk characterization were boiling down the characterization to a point estimate of risk that they presented to risk managers (and the public) without sufficient information concerning uncertainties, methodologies and assumptions.[113] That the form of the risk characterization may be expressed in several ways can be confusing. For example, a risk characterization might be expressed as 1×10^{-6} for an "average" individual or as 1×10^{-6} for the "most exposed" individual.[114] Without explanation such terms used in different regulatory contexts can only serve to confuse risk managers or the public.[115] EPA's policy is now to use consistent risk characterization formats across the agency.[116]

b. Example of Risk Assessment

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113. Habicht Memo, *supra* note 90, at 1-2.

114. *Id.* at 3.

115. In Frank B Cross., Daniel M. Byrd III, & Lester B. Lave, *Discernible Risk—A Proposed Standard For Significant Risk In Carcinogen Regulation*, 43 Admin. L. Rev. 61 (1991)[hereinafter, Cross et al., Discernible Risk]. The authors advocate that federal agencies settle on a "currency of risk," i.e., a standard for expressing risk characterizations. The authors present four possibilities: (1) average lifetime (or perhaps annual) risk - a measure of the probability of incurring cancer for the average member of the exposed population; (2) maximum lifetime (or annual) risk - a measure of the probability of incurring cancer for the maximally exposed member or subgroup of the exposed population; (3) annual expected cancers - a measure of the additional number of cancers to be expected each year in the exposed population, expressed in numeric terms; and (4) reduced life expectancy - a measure of the average life expectancy lost due to cancer in the exposed population, expressed in terms of time. *Id.* at 73-75.

116. Habicht Memo, *supra* note 90, at 3.

An example is helpful to show how the steps of risk assessment work together.[117] Suppose that EPA decides when evaluating clean-up options at a Superfund site to assess the health risks of waste residue from an organic solvent once used to degrease metal parts. Risk assessors begin the hazard identification step by researching the scientific literature for studies concerning the solvent. The risk assessors can hope to find four types of studies:[118] (1) Epidemiological studies of human exposure to the solvent; (2) Animal-bioassay data, i.e, studies of the response of animals to exposure of the solvent; (3) Short-term tests in which the solvent is exposed to bacteria growing in a culture in a laboratory to see if the solvent alters the DNA or causes a mutagenic affect; or (4) Molecular structure comparison studies which compare the molecular structure of the solvent with the structure of known carcinogens or other chemicals known to cause adverse health effects.

Assume the hazard identification step finds several experimental animal studies showing lethal toxicity to the liver at high doses, but no toxic effects below an identifiable "threshold dose." One animal study shows that lifetime exposure by inhala-

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117. Adapted from Richard N. L. Andrews, *Risk Assessment: Regulation and Beyond*, in Environmental Policy in the 1990s: Toward a New Agenda 167, 170-171 (N. Vig & M. Kraft eds.)

118. *See* Managing the Process, *supra* note 88, at 21-23. The four types of studies are also discussed in Cross, Cancer and the Law, *supra* note 68, at 42-50. *See generally* Maugh, *Chemical Carcinogens: The Scientific Basis for Regulation*, 201 Science 1200 (1978) and Maugh, *Chemical Carcinogens: How Dangerous in Low Doses*, 202 Science 37 (1978) (providing excellent and accessible discussions of testing for carcinogens).

tion of lower doses causes a significant increase in lung cancer in mice. A second animal study shows that a lifetime exposure by ingestion causes a significant increase in liver tumors in rats. The only epidemiological data are on exposed workers where two cases of cancer occurred out of 200 workers when one case of cancer might have been expected, but the worker population is too small for this increase to be statistically significant. The short-term tests are mixed with some mutagenicity shown among specific classes of bacteria. The molecular comparison studies show a rough correlation to one known carcinogen. From the studies, EPA decides that the solvent is a "possible" as opposed to a probable or definite) human carcinogen.[119]

During the dose-response assessment, an analyst uses a mathematical model to predict a plausible estimate of human cancer risk by extrapolating from the animal studies. Two forms of extrapolation are need. First, the analyst must extrapolate the effects at a very high maximum tolerated dose to the much lower exposure levels to which humans are likely to be exposed and second, the analyst must employ interspecies extrapolation, to translating the dose in animal experiments to humans. We assume that since the solvent caused cancer in animals, the solvent causes cancer in humans and we assume that high doses used in the animals to produce an increased incidence of cancer

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119. EPA classifies carcinogens into various categories based on the strength of the evidence examined during the risk assessment. *See* Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (1986) and discussion *infra* at text accompanying notes 163-170.

predict at low doses, some smaller, but greater than zero incidence of cancer at low doses. The analyst applies the model incorporating these extrapolations to the animal data to determine a "unit cancer risk." In this example, assume the analyst finds the risk to a human for a lifetime exposure to one milligram per kilogram (mg/kg) of body weight per day to be two in one hundred for lung cancer caused by inhalation (based on the mice studies) and about five in one hundred for liver cancer from ingestion (based on the rat studies).

During the exposure assessment step, another analyst then uses monitoring data and dispersion models to calculate that eighty neighbors may be exposed to about eight ten-thousandths of a mg/kg of body weight per day, 150 workers to about one thousandth mg/kg of body weight per day, and about 50,000 people may be exposed to one to two thousandths mg/kg of body weight from gradual groundwater contamination in drinking water over the next twenty years.

Finally, the calculations are combined in a risk characterization to show numerical estimates of excess lifetime cancer risks. In this hypothetical case, the result might show a risk of eight in one hundred thousand excess cancers in the general population, one in one thousand for the nearby neighbors, and three in one thousand for the workers. Risk assessors then provide these estimates to the risk managers and, if the risk assessors at EPA pay attention to the Deputy Administrator's Guidance of Risk Characterization, the point estimates will be

accompanied by a candid description of the strengths and weaknesses of the data used as well as a description of the uncertainties inherent in the assessment.[120]

In Managing the Process, the NRC recognized that risk assessment contained two general categories of uncertainty: (1) missing or ambiguous information on a particular substance and (2) gaps in current scientific theory.[121] NRC calls the inferential bridges needed to bridge scientific uncertainty **components** and calls the judgments made by scientists or risk assessors among the choices available for components **inference options.**[122] By way of illustration, the NRC gave examples of fifty inference options that exist in the four step risk assessment process while stressing that the list was not exhaustive nor that all components listed would be found in every risk assessment.[123] A brief examination of the fifty examples shows the complexity of the scientific judgment calls and policy that must be made for the process.[124] For each component, a scientist, risk assessor or regulator may choose among two or more options. The options differ as to their degree of conservatism with the most conservative that option which is most protective of human health or of

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120. Habicht Memo, *supra* note 90, at 2-3.

121. Managing the Process, *supra* note 88, at 28. *See also* Guruswamy *supra* note 80 and accompanying text.

122. *Id.*

123. *Id.* at 29.

124. *See infra* Appendix.

the environment.[125] Because of the multitude of scientific and judgment calls in risk assessment and the importance of each decision to the outcome, NRC concluded that these decisions should be made in isolation from those who will later be called upon to perform risk management. For example, a risk manager who must balance economic considerations with risk might be tempted to make his decision easier by shading the risk assessment inference options. By bifurcating the process, the public can then be sure that the risk assessment policies and judgment calls are not influenced by risk management considerations. Risk managers must then work with whatever risk characterization the risk assessors provide and explain contrary decisions against the backdrop of the reasons supporting the Agency's choice of inference options.

NRC recommended that federal agencies create an inference guideline—an explicit statement of a predetermined choice among options that arise from inferring human risk from data that are not fully adequate or not drawn directly from human experience—to avoid selecting inference options for each risk assessment on a case-by-case basis.[126] NRC recognized that agencies might arrive at ad hoc guidelines because an agency might use the same inference options over time, but urged the use of explicit guidelines to inform outsiders and to make the reasoning known

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125. *Id.* at 34.

126. Managing the Process, *supra* note 88, at 51.

for the agency choices.[127] NRC recommended guidelines and not regulations because of the evolving nature of science; agencies must use the time consuming procedures required by the Administrative Procedure Act to create regulations.[128] Because regulations are reciprocally binding on an agency and a private party, science developments might freeze a regulatory effort dependent on risk assessment while the inference options are changed.

Interestingly, the NRC did not make a recommendation on how agencies are to choose inference options when there is no clear indication based on science. NRC mentioned that an agency "could choose a particular approach (e.g. the use of an extrapolation model) solely on the basis of the degree to which it is conservative..."[129] The indiscriminate choice of the most conservative options can, however, be less protective[130] and has been roundly criticized.[131]

V. Development of EPA Risk Assessment Methodology

Even before *Managing the Process* was written, EPA had invested considerable time and effort in developing and defending the assessment of carcinogenic risks. The development of guidelines for other health risk end points, such as mutagenicity had

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127. *Id.* at 52.

128. *Id.*

129. Managing the Process, *supra* note 88, at 37.

130. *See supra* text accompanying note 55.

131. *See supra* Section VI a.

begun to appear as well.[132] For the purposes of highlighting some of the developments in the Agency risk assessment process and to set up recent critiques, selected Agency policy statements are examined below.

a. The 1976 Interim Cancer Assessment Guidelines

As early as 1974 EPA had begun to develop a series of cancer "principles" to use in the defense of challenges to its actions against DDT and other pesticides.[133] In May 1976 the Agency adopted interim carcinogen assessment guidelines.[134] The 1976 Guidelines referred to a "weight-of-evidence" approach for carcinogens and supported the now prevalent use of high dose animal bioassays, short-term tests and mathematical models to extrapolate to human levels of exposure.[135] Risk assessors applying the 1976 Guidelines were asked to weigh information from existing studies to answer two questions: "(1) How likely is the agent to be a human carcinogen and (2) If the agent is a human carcinogen, what is the estimated impact on human health?"[136]

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132. *See* EPA, Proposed Guidelines for Mutagenicity Risk Assessments, 45 Fed.Reg. 74,984 (1980).

133. Sheila Jasanoff, The Fifth Branch 182 (1990))(citing Nathan J. Karch, Explicit Criteria and Principles for Identifying Carcinogens: A Focus for Controversy, in 2a National Academy of Science - National Research Council, Decision Making in the Environmental Protection Agency 119-206 (1977).

134. Interim Procedures and Guidelines, Health Risk and Economic Impact Assessments of Suspected Carcinogens, 41 Fed. Reg. 21,402-21,405 (1976) [hereinafter 1976 Guidelines].

135. *Id.* at 21,404-05.

136. *Id.* at 21,405.

b. Water Criteria Documents - Appendix C

The Agency updated its approach to human health assessment when in 1980 it released several water quality criteria documents required under the Clean Water Act.[137] In Appendix C of the Water Criteria Documents, EPA looked at three health risk end points—carcinogenicity, toxicity (all adverse health effects other than cancer) and organoleptic effects (impacts on taste and smell of water).[138] EPA contrasted the no-threshold level for cancer with a safe or no-effect level for other noncarcinogenic toxics. Unlike carcinogens, for which EPA presumes no safe level can be established; for noncarcinogens, EPA assumes a physiological reserve capacity exists within an organism which can be depleted before an adverse effect appears.[139] This allows EPA to adopt water quality standards for noncarcinogens set at the threshold of exposure to a substance at which there no observable adverse effect.

Appendix C provides an in depth analysis of the uses and weaknesses of epidemiological data. Epidemiological data are derived from studies that compare two similar human populations

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137. Notice of Availability of Water Quality Criteria Documents at Appendix C—Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents, 45 Fed. Reg. 79,347-79,379 (1980)[hereinafter Appendix C]. Under the Clean Water Act, the EPA is required to issue criteria for water quality reflecting the latest scientific knowledge on identifiable effects on health and welfare from the presence of pollutants on water. 33 U.S.C.A. § 304(a) (West Supp. 1992).

138. *Id.* at 79,347.

139. *Id.* at 79,347-48.

that are alike except for their exposure to the substance of interest.[140] Proof that a substance is a carcinogen is best obtained from epidemiological studies because it provides direct proof that a substance causes cancer in humans, i.e., there are no extrapolations needed from animal studies; but other problems exist.[141] First, epidemiology cannot be used to predict adverse effects until after humans have been exposed, and one cannot ethically conduct potentially hazardous experiments on humans.[142] Second, if exposure is widespread, it may be impossible to find a control group, i.e., a group that has not been exposed to a substance, against whom one can measure differences of effect.[143]

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140. *See* Cross, Cancer and the Law, *supra* note 68, at 45-46. Professor Cross described the two types of epidemiologic studies—cohort studies and case-control studies:

> In cohort studies, the investigator first identifies two populations that are similar except for exposure to a given substance. These groups are then followed to find any increases in cancer incidence. For example, an investigator might compare cancer rates between construction workers using asbestos products and workers doing similar construction work but using no asbestos products....In case control studies, the investigator begins by taking a population that suffers from cancer. Then, he or she takes a group of people of similar age, sex, and race who do not have cancer. The investigator can then seek out unique exposures in the group with cancer that explains their disease.

Id. Cohort studies are more reliable than case-control studies, but more difficult to perform. *Id.* Professor Cross illustrates the weakness of case-control studies with one such a study that found hospital patients who had pancreatic cancer drank more coffee than did patients with other digestive diseases. Rather than discovering coffee caused cancer, the investigators may have only discovered that other digestive diseases preclude drinking coffee! *Id.*

141. Appendix C, *supra* note 137, at 79,349.

142. *Id.*

143. *Id.*

For example, epidemiology can prove cancer is more prevalent in cities, but studies cannot be designed to determine what characteristic of city life is the cause.[144] Third, measuring the doses that humans have received is difficult when looking at historical data.[145] Often there is no mechanism to verify the magnitude, the duration, or even route of exposure. Fourth, usually experimenters find it hard to identify small changes in common effects that may be important if the population is large.[146] Epidemiology can detect only large increases in cancer. The power of detection is related to the size of the population exposed and the incidence of cancer. Because it is hard to study large portions of the population, small increases in small populations are often statistically insignificant or, in other words, the increases may merely be due to chance.[147] Fifth, interactions in an epidemiological experiment cannot be controlled as in laboratory experiment, i.e., one cannot be sure that other substances or activities were not the cause of the adverse effect (confounding factors).[148] Sixth, negative results

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144. Cross, Cancer and the Law, *supra* note 68, at 46-47.

145. Appendix C *supra* note 137, at 79,349.

146. *Id.*

147. *Id.* This is the reason that the epidemiological study among workers given in the example was considered statistically insignificant. *See supra* page 34.

148. *Id.*

from an epidemiological study cannot demonstrate lack of effect.[149] Again, it's difficult to prove a negative.

Appendix C also discussed the choice of extrapolation models to be used when analyzing nonthreshold effects of cancer. First, the Agency stated its goal for setting criteria for carcinogens as the water concentration of a pollutant which is estimated to cause a lifetime carcinogenic risk of 10^{-5}.[150] Next, the Agency assumed that, unless evidence exists to the contrary, if a carcinogenic response occurs at the dose levels used in an animal study, then proportionately lower responses will also occur at all lower doses, i.e., the Agency would assume a no-threshold linear relationship.[151] The Agency also admitted that there is "no really solid scientific basis for any mathematical extrapolation model which relates carcinogen exposure to cancer risks at the extremely low levels of concentration found when evaluating environmental risks."[152] However, the Agency added,

> For practical reasons, such low levels of risk cannot be measured directly either using animal studies or epidemiologic studies....Because it has the best, albeit limited, scientific basis of any of the current mathematical extrapolation models, the linear non-threshold model has been adopted as the primary basis for risk extrapolation to low doses of the dose-response relationship. The risk assess-

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149. *Id.*

150. *See* Appendix C *supra* note 137, at 79,350. Earlier in the Water Criteria Documents the Agency was careful to state that the 1 in 100,000 risk was not an Agency judgment as to acceptable risk. *Id.* at 79,323.

151. *Id.*

152. *Id.*

> ments made with this model should be regarded as conservative, representing the most plausible upper limit for the risk; i.e., the true risk is not likely to be higher than the estimate but it could be smaller.[153]

The Agency then went on to explain the operation of "the improved multistage model" it chose to describe the linear, non-threshold relationship.[154] The guidelines in Appendix C remain remarkably current and demonstrate the operation of the statement and use of explicit inference guidelines for the risk assessment process as recommended by the NRC. Appendix C also showed the Agency's preference for choosing conservative models in the absence of scientific evidence.

c. The 1986 Carcinogen Risk Assessment Guidelines

The Agency adopted the NRC recommendations in *Managing the Process* by publishing five sets of inference guidelines in 1986. The guidelines were published for carcinogen risk assessment,[155] estimating exposures,[156] mutagenicity risk assessment,[157] health

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153. *Id.*

154. *Id.* at 79,350-79,353.

155. EPA, Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992 (1986) [hereinafter 1986 Guidelines]. *See* Latin, *Good Science*, *supra* note 58 (arguing that risk assessment should not be divided from risk management because social policy considerations must play as prominent a role in the choice of risk estimates as in the ultimate determination of which predicted risks should be deemed unacceptable.) Professor Latin offers social policy criteria that agencies could use to supplement scientific evidence after evaluating the EPA Carcinogen Risk Assessment Guidelines. *Id.*

156. EPA, Guidelines for Exposure Assessment, 51 Fed. Reg. 34,042 (1986).

157. EPA, Guidelines for Mutagenicity Risk Assessment, 51 Fed. Reg. 34,006 (1986).

assessment of suspect developmental toxicants,[158] and health risk assessment of chemical mixtures.[159] Each of the guidelines stressed that risk assessment would be carried out independently from considerations of any regulatory action, outlined the general principles and procedures to guide Agency scientists in performing risk assessments and provided specific guidance on choice of inference options for various components of risk assessments. The format used in the 1986 guidelines is still used by the Agency today; several of the guidelines have been updated to reflect changing science or to provide more detail in methodology.[160]

The 1986 Guidelines for Carcinogen Risk Assessment [hereinafter 1986 Guidelines] emphasized that risk assessments are conducted on a case-by-case basis, giving full consideration to all relevant scientific information. Agency scientists are to identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.[161] In

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158. EPA, Guidelines for the Health Assessment of Suspect Developmental Toxicants, 51 Fed. Reg. 34,028 (1986).

159. EPA, Guidelines for the Health Risk Assessment of Chemical Mixtures, 51 Fed. Reg. 34,014 (1986).

160. *See e.g.*, EPA, Guidelines for Developmental Toxicity Risk Assessment, 56 Fed. Reg. 63,798 (1991); EPA, Guidelines for Exposure Assessment, 57 Fed. Reg. 22,888 (1992). The Guidelines for Carcinogen Risk Assessment have not been updated, but have been under review since 1988. *See* EPA, Notice of Intent to Review Guidelines For Carcinogen Risk Assessment, 53 Fed. Reg. 32,656 (1988).

161. EPA, 1986 Guidelines, *supra* note 155, at 33,992.

the 1986 Guidelines, EPA explicitly discussed the weight-of-evidence approach alluded to in the 1976 Guidelines.[162] The weight-of-evidence approach provides an example of inference options at work.

EPA classifies substances into five groups based on the overall weight of evidence of carcinogenicity from animal and human studies. The five groups are: Group A—Carcinogenic to Humans, Group B—Probably Carcinogenic to Humans, Group C—Possibly Carcinogenic to Humans, Group D—Not Classifiable as to Human Carcinogenicity, Group E—Evidence of Non-Carcinogenicity for Humans.[163] A substance is placed in Group A "only when there is sufficient evidence from epidemiologic studies to support a causal association between exposures to the agents and cancer."[164] Group B substances can fall into two subcategories. Group B1 is for substances for which there is limited epidemiologic evidence of carcinogenicity, but there exists "sufficient" evidence of carcinogenicity from animal studies and relevant data studies of short-term tests, structure-activity (structure comparison to known carcinogens) or other "indicator" tests.[165] Group B2 is reserved for substances for which there is "suffi-

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162. *See supra* text accompanying note 134.

163. EPA, 1986 Guidelines, *supra* note 155, at 33,996.

164. *Id.* at 34,000.

165. *Id.*

cient" evidence from animal studies and for which there is "inadequate evidence" or "no data" from epidemiologic studies.[166]

Group C is used for substances with limited evidence of carcinogenicity in animals in the absence of human data and relies upon the widest variety of evidence including: a malignant tumor response in a single well conducted experiment that does not meet conditions for "sufficient evidence,"[167] tumor responses of marginal statistical significance in studies having inadequate design or reporting, benign but not malignant tumors for a substance showing no response in short-term tests for mutagenicity or responses of marginal statistical significance in a tissue known to have a high or variable background rate (of tumors).[168] Group E substances are so classified if two adequate animal tests using different species or an adequate animal test and epidemiologic study show no evidence of carcinogenicity.[169] EPA was cautious in noting again the difficulty of proving a false negative and warned, "the designation of an agent as being in Group E . . . should not be interpreted as a conclusion that the agent will not be a carcinogen under any circumstances."[170]

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166. *Id.*

167. *Id.* A study might not be considered to be sufficient if, for example, it was conducted with too few animals or the experiments were restricted by inadequate dosage levels. *Id.* at 33,999.

168. *Id.* at 34,000.

169. *Id.*

170. *Id.*

The 1986 Guidelines describe a two part process for risk characterization. First, the risk assessors provide numerical estimates. The guidelines left the choice of format as an option; the risk assessors could choose unit risk (the excess lifetime risk due to a continuous constant lifetime exposure to a given dose), a dose corresponding to a given level of risk, an individual or population risk or some combination of the three.[171] The second part requires the numerical estimate to be accompanied by discussion and interpretation to afford risk managers "some insight into the degree to which the quantitative estimates are likely to reflect the true magnitude of human risk." The Agency has had to remind its risk assessors of this responsibility.[172] The numerical estimate includes the Group classification. For example, a lifetime individual risk of 2 x 10^{-4} (1 in 10,000) resulting from exposure to a probable human carcinogen (Group B2) would be presented as 2 x 10^{-4} [B2].[173]

The remainder of the 1986 Guidelines followed the NRC, *Managing the Process* format with sections discussing inference options for hazard identification, dose-response assessment and exposure assessment. In a section on long-term animal studies, EPA discussed the implications of using maximum tolerated dosages (MTD). A MTD is the highest dose that can be given to an animal

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171. *See* Cross, et al., *Discernible Risk*, *supra* note 116.

172. *See* Habicht Memo, *supra* note 90, at 2-3.

173. EPA, 1986 Guidelines, *supra* note 155, at 33,999.

without causing significant noncarcinogenic effects in the animal.[174] MTDs are used to increase the statistical power of a study because studies using low dosages approximating human exposure would need a tremendous number of animals to produce statistically significant results. Even with a large animal study with high dosages, tests are unable to detect cancer increases of much less than 15 or 20 percent; a dose of a substance that increases cancer rates by only one or two percent in humans would go unobserved in animal tests.[175] But EPA warned that studies showing negative results would not be acceptable if the animals were exposed to levels above the MTD high enough to impair animal survival.[176] The Agency also reaffirmed its choice of extrapolation model: "In the absence of adequate information to the contrary, the linearized multistage procedure will be employed.[177]

VI. Critique and Response

One conclusion that can be drawn so far is that risk assessment methodology asks much of uncertain data and uncertain scientific models. As seen in Section III, conservatism can be more or less protective depending on what assumptions are true. The critique of risk assessment and risk management can be viewed as arguments about the strength of Dr. Whipple's three assump-

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174. *See* Cross, Cancer and the Law, *supra* note 68, at 43.

175. *Id.* at 43.

176. EPA, 1986 Guidelines, *supra* note 155, at 33,995.

177. *Id.* at 33,997.

tions. No one suggests that there is a better tool to make the risk-based decisions required by the statutes; the question is how to view the results produced by the process. William Ruckelshaus, former Administrator of EPA characterized the two polar opposites on the issue of conservatism in risk assessment:

> The first, usually proffered by the regulated community, argues that regulation ought not to be based on a set of unprovable assumptions, but only on connections between pollutants and health effects that can be demonstrated under the canons of science in the strict sense. It points out that for the vast majority of chemical species, we have no evidence at all that suggests effects on human health from exposures at environmental levels. Because many important risk assessments are based on assumptions that are scientifically untestable, the method is too susceptible to manipulation for political ends and, the regulated community contends, it has been so manipulated by environmentalists. The second viewpoint counters that waiting for evidence of human health effects amounts to using the nation's people as guinea pigs, and that is morally unacceptable. It proposes that far from overestimating the risks from toxic substances, conventional risk assessments underestimate them, for there may be effects from chemicals in combination that are greater than would be expected from the sum of all chemicals acting independently. While approving of risk assessment as a priority-setting tool, this viewpoint rejects the idea that we can use risk assessment to distinguish between "significant" and "insignificant" risks. Any identifiable risk ought to be eliminated up to the capacity of available technology to do so. Risk assessment is necessarily dependent on choices made among a host of assumptions and these choices will inevitably be affected by the values of the choosers, whether they be scientists, civil servants, or politicians.

This section discusses arguments that question whether using conservative options in the risk assessment process is warranted; the arguments focus on uncertainties within the science. Risk management issues focus on the impacts caused by high cost of regulatory programs based on estimates of risk drawn from the risk assessment process.

a. The 1990 OMB Report

In 1990, the Office of Management and Budget ("OMB")[178] issued a controversial report in which OMB made three observations concerning the "continuing difficulties that plague the practice of risk assessment":

> (1) The continued reliance on conservative (worst-case) assumptions distorts risk assessment, yielding estimates that may overstate likely risks by several orders of magnitude.
> (2 Conservative biases embedded in risk assessment impart a substantial "margin of safety". The choice of an appropriate margin of safety should remain the province of responsible risk management officials, and should not be preempted through biased risk assessments.
> (3) Conservatism in risk assessment distorts the regulatory priorities of the Federal Government, directing societal resources to reduce what are often trivial carcinogenic risks while failing to address substantial threats to life and health.[179]

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178. The role of OMB in the regulatory process is defined by Executive Order 12,291, 46 Fed. Reg. 13,193 (February 17, 1981). OMB has authority to review new regulations proposed by executive agencies to ensure:

> (a) administrative decisions are based on adequate information concerning the need for and consequences of proposed government action;
> (b) regulatory action shall not be taken unless the potential benefits to society for the regulation outweigh potential costs to society;
> (c) regulatory objectives shall be chosen to maximize net benefits to society;
> (d) among alternative approaches to any given regulatory objective the alternative involving least net cost to society shall be chosen: and
> (e) agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.

Id. at 13,194.

179. U.S. Office of Management and Budget, *Regulatory Issues in Risk Assessment and Risk Management* in Regulatory Program of the

(continued...)

The OMB Report examined agency use of animal bioassay data noting first several advantages to animal testing: animal testing allows scientists to estimate risks before human health effects are observed in contrast to epidemiological studies which detect health effects after they appear in humans; animal testing is conducted under controlled conditions in laboratories which can avoid confounding factors present in many epidemiological studies; and the relatively short life spans of laboratory animals allow scientists to observe long term effects in just a few years instead of the 70 year plus lifetimes of humans.[180] The OMB critiques of animal testing were tied to uncertainties associated to the familiar assumptions that must be made if the results from animal tests will have any statistical significance. The OMB Report noted that there exists no accepted scientific basis for the assumption that results can be meaningfully extrapolated from test animals to humans.[181]

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179. (...continued)
United States Government, April 1, 1990 - March 31, 1991, Executive Office of the President 13-26 (1990)[hereinafter OMB Report].

180. *Id.* at 15.

181. *Id.* (citing Bruce Ames, Renae Magaw, and Lois Swirsky Gold, *Ranking Possible Carcinogenic Hazards*, 236 Science 271 (1987). The authors in *Ranking Possible Carcinogenic Hazards* made the case against the use of laboratory animals as follows:

> Quantitative extrapolation from rodents to humans, particularly at low doses, is guess work, that we have no way of validating. It is guesswork because of lack of knowledge in at least six major areas: (i) the basic mechanisms of carcinogenicity, (ii) the relation of cancer, aging, and lifespan; (iii) the timing and order of the steps in the carcinogenic process that are being accelerated; (iv) spe-

(continued...)

The validity of interspecies comparisons, e.g., from laboratory rats or mice to humans, is based on the assumption that a substance that causes an adverse health effect in an animal will also cause an adverse effect in a human. While the assumption seems true in an intuitive sense, several factors render the assumption unreliable. First, many of the species have different metabolic processes than humans. This becomes important when the cancer causing agent is from a metabolite of the substance rather than the substance itself. If humans do not metabolize the substance into the same metabolite as the tested species, the assumption may no longer hold. The specter of the false negative still remains because humans may develop cancer from the substance itself or another metabolite.[182] Furthermore, animals may produce tumors in organs not found in humans. OMB questioned whether the formation of tumors in the zymbal gland of a rat should have any significance to the human species which has no

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181. (...continued)
cies differences in metabolism and pharmacokinetics; (v) species differences in metabolism and pharmacokinetics; and (vi) human heterogeneity—for example, pigmentation affects susceptibility to skin cancer from ultraviolet light. These sources of uncertainty are so numerous and so substantial, that only empirical data will resolve them, and little of this is available.
Bruce N. Ames, Renae Magaw, & Lois Gold Swirsky, *Ranking Possible Carcinogenic Hazards*, 236 Science 271 (1987) reprinted in Readings in Risk 76 at 83. (Theodore S. Glickman and Michael Gough eds., 1990)[hereinafter Ames, et al., *Ranking Possible Carcinogenic Hazards*].

182. *See* Ames, et al., *Ranking Potential Carcinogenic Hazards, supra* note 181, at 85 (stating that for years standard rodent studies failed to reliably detect the risk of cancer from alcohol and tobacco.).

zymbal gland.[183] OMB also examined the issue of extrapolating from one exposure pathway in an animal to another exposure pathway in a human. OMB questioned the validity of relying on studies showing an animal developed cancer by inhalation if the only likely route of exposure to a human is through ingestion.[184]

The best that has been said for interspecies comparisons is that for many substances the correspondence between animal and human carcinogen potency is quite close.[185] As science improves knowledge may be gained explaining the differences in metabolic processes between species, but in the absence of knowledge of mechanism for any particular substance the extrapolation from humans remains largely uncertain.

OMB examined the preferred use of highly sensitive test animals, noting that in one test species, one-third of the male animals spontaneously develop liver tumors.[186] Using sensitive animals increases the power of a study because it is more likely that a carcinogen will evoke a response.[187] OMB observed that the use of such animals was conservative in another way; because

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183. OMB Report, *supra* note 179, at 19.

184. *Id.*

185. *See* Cross, Cancer and the Law *supra* note 68, at 59. (stating that current studies on tobacco and asbestos have found extrapolation from animal bioassays to be an accurate predictor in humans).

186. OMB Report, *supra* note 179, at 17.

187. Sensitive animals increase the sensitivity of the test, i.e., the greater the sensitivity of the animals the less likely the test will produce false negatives. *Id.* at 18 n.46.

sensitive animals more easily develop cancer in the presence of a carcinogen and increase the power of a study, scientists will search for and develop increasingly sensitive species.[188] The OMB critique seems suspect because scientists will always have to account for the background level of cancers in the control group.

OMB next examined use of the maximum tolerated dose (MTD), concluding that the combination of highly sensitive species and MTDs predispose animal bioassays to discover carcinogenic effects.[189] Scientists are engaged in an ongoing debate on the issue of whether MTDs, which evoke mild toxic effects but do not significantly alter an animals growth or development, are a substantial cause of the increased incidence of cancer found in animal bioassays.[190]

OMB criticized EPA guidelines which give the most weight to studies using the most sensitive species. EPA employs the conservative option of considering a substance a probable carcinogen when one species or gender show a statistically significant increase in tumors despite other studies which show negative results.[191] OMB characterized this presumption as establishing "a virtually irrebuttable presumption in favor of the carcinogen-

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188. *Id.*

189. *Id.* at 18.

190. *See* Carcinogens and Human Health: Part 2, 251 Science 10 (Jan. 4 1991) (letter from David P. Rall and response by Bruce N. Ames & Lois S. Gold); Carcinogens and Human Health: Part 3, 251 Science 606 (Feb. 8, 1991) (letter from Vincent J. Cogliano et al. and response by Bruce N. Ames & Lois S. Gold).

191. EPA, 1986 Guidelines, *supra* note 155, at 33,996.

esis hypothesis."[192] OMB also examined EPA guidelines that aggregate benign and malignant tumors unless a strong scientific case can be made against the practice.[193] This option assumes that a benign tumor might have become malignant. A less conservative option might assume the converse in the absence of scientific evidence. OMB also looked at the practice of pooling tumor incidence across sites. This practice is based on the assumption that cancer induction is independent across sites and unrelated to metastasis or to the same biological mechanism. OMB insinuated that such an assumption is unwarranted. The difficulty here is that no can know if a carcinogen is site specific with certainty without a tremendous volume of data. For instance, a substance like tobacco which is associated most often with lung cancer is now being linked with cancers in the bladder and pancreas.[194]

OMB critiqued the choice of and scientific basis for using a linear dose-response model. First, OMB concluded that because no scientific model is accepted as being superior to another, the choice of model should be a policy issue rather than a scientific issue.[195] OMB observed that the Agency choice of the linearized multistage model was biased because of its inherent conservatism at low doses and the routine use of the "linearized" form in

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192. OMB Report, *supra* note 179, at 18.

193. *Id.* at 19.

194. *See* Cross, Cancer and the Law, *supra* note 68, at 20.

195. OMB Report, *supra* note 179, at 19.

which the 95 percent upper bound is used instead of the unbiased estimate.[196]

As noted earlier, the Agency has adopted a "one-hit" or "no-threshold" hypothesis for carcinogens, because there is no known safe threshold for exposure to a carcinogen.[197] Once the assumption is made to extrapolate from the high doses studied in animals to the much smaller exposures likely in humans, a choice from available models must be made. A linear relationship shows that as the dose grows smaller the incidence of cancer grows proportionately

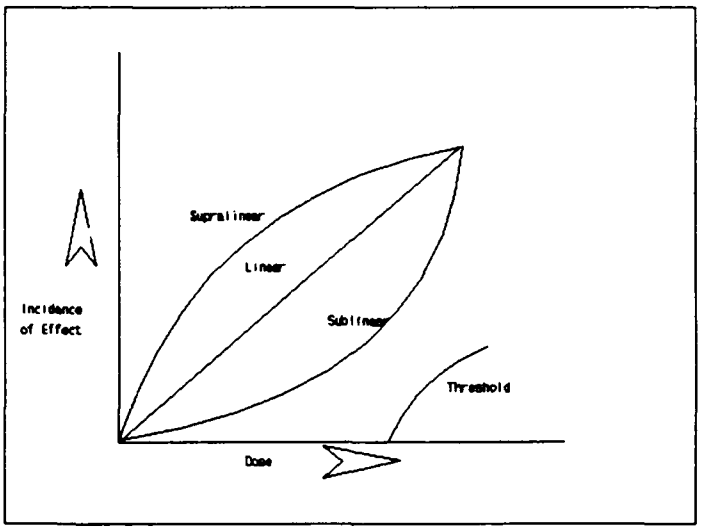

Figure 1

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196. *Id.*

197. *See* Cross, Cancer and the Law, *supra* note 68, at 54. Professor Cross notes:

> Occasionally a scientist suggests the presence of a safe threshold for a carcinogen. This is especially true if a substance's metabolite is carcinogenic and if a threshold can be demonstrated for the relevant metabolic processes. Bodily repair mechanisms also provide some support for a threshold. While theoretically logical, there is seldom, if ever, convincing scientific evidence of such a metabolic threshold for any specific substance. Dr. Arnold Brown thus declared that he believes thresholds do exist for carcinogens but conceded that "no empirical approach is available to demonstrate a threshold.

Id. (citing Arnold Brown, *The Meaning of Risk Assessment*, 37 Oncology 302, 303 (1980)).

smaller appearing as a straight line on a graph through the plotted incidences derived from the animal studies. However, a supralinear or sublinear curve or what is known as a log-probit curve (half of a bell-shape) might come closer to the true relationship. (*See* Figure 1).

In the 1986 Guidelines, EPA recognized the best fit of lines or curves through these data points is not an effective means of discriminating among models and recommended that a different model be used if the choice was based on available pharmacokinetic or metabolism data; however, in the absence of such information, the linearized multistage model is used.[198] The 1986 Guidelines also recommended showing estimates from more than one model to give risk managers a more complete picture of the range of potential risk.[199] However, this guidance was often disregarded in favor of "point estimates" based on upper confidence limits derived from the linearized multistage model.[200]

A multistage model involves fitting a polynomial to a data set with the number of stages identified by the number of terms in the polynomial; the stages are derived from the number of dose levels used in the animal study.[201] Better studies use four groups of animals: one set receives the MTD, a second set receives one-half the MTD, a third set receives one-fourth the MTD

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198. EPA, 1986 Guidelines, *supra* note 155, at 33,998.

199. *Id.*

200. *See* Habicht Memo, *supra* note 90, at 1-3.

201. OMB Study, *supra* note 179, at 19.

and the fourth set receives nothing and is observed as a control. Because of the expense of conducting animal studies,[202] studies with more than three groups of dosed animals are rare.[203] Three groups of dosed animals provides only enough information to put together a two stage model so it is rare to see models with more than two stages.[204]

OMB applied five different models to the same set of data and found estimates of risk at moderate doses varied by more than two orders of magnitude. At smaller doses estimates widened to the point that two models showed essentially no excess cancer risk while two other models showed lifetime cancer risks in excess of one in a thousand. OMB concluded that since none of the five models could be distinguished on the basis of science, the choice of a model "is therefore a pivotal policy decision."[205]

The linearized multistage model is interpreted using a risk estimate which is in the 95 percent upper confidence limit (UCL) instead of the maximum-likelihood estimate (MLE). OMB severely criticized this practice for relying on a "biased estimate"

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202. The price range for animal bioassays in 1988 was between $470,000 and $1.1 million. Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 Mich L. Rev. 1795 n.65 (1989)

203. OMB Study, *supra* note 179, at 19.

204. *Id.*

205. *Id.* at 20.

instead of a an unbiased estimate of risk. Professor Adam Finkel has explained the difference between the UCL and the MLE:

> ...choosing to describe an uncertain quantity by the 95th percentile of its probability distribution merely reflects the conscious or tacit evaluation that an error of underestimation (the five percent chance the "truth" exceeds the summary value) is 19 times as bad as an error of overestimation....The maximum likelihood estimator (MLE) advocated by several revisionists is, in certain contexts such as sampling error in animal bioassay data, the mode of the relevant uncertainty distribution. The mode reflects a different value judgment—that one should minimize the probability of an error, without regard to its type (over- or underestimation) or its magnitude.[206]

OMB found the use of the UCL in the linearized multistage model inflates low-dose risk estimates by a factor of two or three when the MLE of the linear term is positive and increases the low-dose risk estimates by several orders of magnitude when the MLE of the linear term is zero; OMB generally concluded that the linearized multistage model presumes "a margin of safety" that "usurps from policy-makers the authority and responsibility for risk-management decisions."[207] However, scientists defend the use the linear multistage model because of the danger of drawing conclusions from small sets of data.

Risk assessors may use the MLE or the UCL to estimate the potency of a particular substance at dosage levels lower than that administered to the animals during testing. The MLE is the slope of the straight line drawn through the animal data; the UCL

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206. Finkel, *supra* note 58, at 437. The mode is the single value within an uncertainty distribution deemed more likely to occur than any other. *Id.*

207. OMB Report, *supra* note 179, at 21.

is the slope of a steeper line running through an alternate set of data.[208] The alternate set of data represents a probability that if the animal tests had been run on other occasions, exposure to the substance in question would have caused a greater carcinogenic response.

Using an example, assume a hypothetical animal study in which two of fifty rodents developed tumors providing a best estimate that each rodent had a four percent chance of developing cancer.[209] Assuming the true risk to be four percent, if the study could be repeated 100 times, on about five occasions the animals would develop five or more tumors (assuming the animal studies fall in a normal distribution). If the study actually conducted had been one of these five studies, the conclusion would have been that the rodents had a risk of ten percent of developing cancer. The UCL provides for the possibility that a researcher has performed a study with "lucky" rodents; and is no more or less than the lower bound on the exact value one would call the best estimate on five occasions if one had performed the same experiment one hundred times.

Professor Finkel likened using a UCL to the decision faced by a baseball team owner who is asked by a player to renegotiate his contract because he is batting .800 after playing the first two games of the season: the owner would think it prudent to wait

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208. Finkel, *supra* note 58, at 439.

209. Example adapted from that found in Finkel, *supra* note 58 at 439-40.

for the player to maintain that hitting average for a 100 or so at-bats before considering the offer because experience tells the owner that the player's average will drop as the season continues.[210] Unfortunately because of the time and cost of performing animal bioassays, Professor Finkel points out that we will never get a "full season's" worth of data on a chemical.[211] Professor Finkel concluded that the MLE is really a more gratuitous estimate, because it ignores how much the risk estimate might differ if more data were available.[212]

OMB completed its examination of the use of animal bioassay data by comparing the two commonly used approaches for converting animal doses to human-dose equivalents: body weight conversion and surface area conversion.[213] "Dose-scaling" is necessary because one milligram of an agent will have greater impact on a thirty gram rodent than on a seventy kilogram human.[214] EPA scales on the more conservative basis of relative surface area with doses expressed in terms of milligrams per square meter of surface area; the Food and Drug Administration uses the less conservative basis of relative weights expressed in milligrams

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210. *Id.* at 440.

211. *Id.*

212. *Id.* at 441.

213. OMB Report, *supra* note 179, at 22.

214. *See* Michael Gough, *How Much Cancer Can EPA Regulate Away?*, 10 Risk Analysis 1 (1990).

per kilogram of body weight.[215] OMB found that despite the lack of scientific evidence to indicate which method is better, the more conservative option is often applied reflexively.[216]

OMB next examined issues arising from human exposure estimates noting that as a general principal estimates of human exposure should be based on the most likely scenario, with appropriate consideration of uncertainty.[217] OMB found, however, that agencies compound conservative assumptions when real-world data is unavailable; because of the multiplication effect from uncertainty to uncertainty, OMB found that even small overstatements of exposure at several stages will yield a substantial overestimate of actual exposure.[218] OMB also criticized EPA for using data from "hot spots" (available because hot spots receive greater study)) to develop more general national estimates and for assuming that exposures to chemicals that degrade after release into the environment remain constant over time.[219]

Next OMB looked at the Agency practice of basing risk estimates on the upper-bound lifetime cancer risk to the maximum-

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215. *Id.* The author has provided a table showing comparing the sometimes dramatic differences the choice of dose-scaling option can make in arriving at a risk estimate.

216. OMB Report, *supra* note 179, at 22 (citing EPA, 1986 Guidelines, 51 Fed. Reg. at 33998 (1986)).

217. *Id.* at 22. OMB was criticizing EPA's 1986 Exposure Assessment Guidelines, *supra* note 156. The Guidelines were superseded by new Exposure Assessment Guidelines on May 29, 1992, *supra* note 160.

218. *Id.*

219. *Id.*

exposed individual (MEI), "the person whose exposure is greater than all the others."[220] OMB observed that because environmental regulations are often justified using estimates of risk posed to a mythical MEI, actual risks may be much lower than what decisionmakers and the general public perceive them to be.[221]

OMB illustrated the dangers of employing overly conservative risk assessment practices by discussing misordered priorities and perverse outcomes. First, OMB noted that overstating risks logically leads to inefficient regulatory choices.[222] Overstatement of the risks associated with suspected carcinogens can lead regulators to apply more resources than necessary to control such substances at the expense of other activities posing greater actual risk.[223] Second, OMB examined EPA's regulation of ethylene dibromide (EDB) to show the perverse outcome that regulatory action based on overstated risks can lead to greater actual risks. EDB, before it was banned, was used to combat the presence of vermin and molds in food and was classified as a pesticide. Molds in food produce a natural carcinogen, aflatoxin B, which is especially prevalent in peanuts and peanut butter. OMB noted that the human cancer risk from the aflatoxin B in one peanut butter sandwich is about 75 times greater than a full

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220. *Id.* *See supra* discussion at note 116.

221. *Id.* at 22.

222. *Id.* at 24.

223. *Id.*

day's dietary exposure from EDB.[224] OMB asked whether risk managers should have accepted the relatively small risk from EDB to control the greater risk from aflatoxin B. OMB also asserted that reliance on estimates of risks to the MEI could lead to increased population risks. As an example, OMB showed that EPA's recent regulation of the disposal of sewage sludge would probably create greater population risk because setting a too protective standard from risks from sludge disposal in landfills can cause a shift to sludge disposal by incineration.[225] However, these two examples are a bit misleading. Better risk estimates will not necessarily cause risk managers to consider alternatives that may be encouraged or discouraged by a proposed regulation. Risk managers may be limited by the language of the particular statute they are implementing to control the risk of interest to the statute. Risk balancing standards allow consideration of the benefits of a substance. For example, under FIFRA, risk managers may consider control of aflatoxin as part of the benefit analysis of the pesticide.[226] However, under the FFDCA and its "Delaney Clause", no discretion is permitted risk managers when a pesticide is known to be a carcinogen no matter how small the exposure or risk.[227]

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224. *Id.* That natural carcinogens like aflatoxin may pose a far greater risk than synthetic carcinogens is discussed in Ames, et al., *supra* note 181 at 85.

225. *Id.*

226. *See supra* text accompanying notes 34.

227. *See supra* discussion at note 20.

OMB concluded its report by acknowledging that risk assessment remains a powerful tool for estimating risk in a technologically advanced society and made four general recommendations. First, OMB recommended that risk assessment produce unbiased expected value estimates of risk, instead of using worst-case analysis based on extremely conservative models of risk and exposure assessment; second, OMB asked that weight-of-evidence assumption be reassessed to give more weight to well conducted studies that showed negative results; third, OMB stressed that risk assessors make full disclosure of all assumptions and judgments used in creating a risk assessment; finally, OMB recommended that risk managers examine closely the likely result of regulatory alternatives to ensure a regulatory action in one area does not make matters worse in another.[228]

Several arguments exist to dispute OMB's assessment that the risk assessment process is too conservative. The following three are offered as examples. First, the risk assessment process assumes that multiple risks are additive; however, some chemical combinations have a synergistic effect. For example, tobacco and asbestos have been found to create a risk three times higher than one would expect by adding the risks from each substance separately.[229] Conservative risk assessment methodologies may compensate for the inability to test all possible chemical combinations

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228. *Id.* at 25-26.

229. Finkel, *supra* note 58, at 447 (citing Selikoff, *Carcinogenic Risk Management in the United States*, in Management of Assessed Risk for Carcinogens 290 (1981)).

for synergistic effects, but perhaps this "adjustment" is best left to a risk manager. Second, the assumption that rodents are more sensitive than humans may not be true for highly susceptible human subpopulations.[230] This argument raises the question of whether standards should be set for the "average" population or for the "most highly susceptible" subpopulation. Again, this adjustment seems to be best left to the risk management side of the equation. Third, rodent tests are typically terminated after two years even though the normal lifespan is three years; this may be equivalent to exposing humans for only two-thirds of the average human lifespan.[231] The entire debate was summarized by one scientist who gave the comforting opinion that the current risk assessment procedures possess unknown degrees of both nonconservatism and conservatism.[232]

One can conclude that, as of the time OMB examined risk assessment practices, EPA had chosen predominately conservative options when faced with uncertainty. It is difficult to tell the net impact from any mixture of conservative and nonconservative

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230. Center for Risk Analysis, Harvard School of Public Health, *OMB vs. the Agencies: The Future of Cancer Risk Assessment, Summary and Highlights of Discussion of the Workshop to Peer Review the OMB Report on Risk Assessment and Risk Management* 15 (June 1991) (comments of Dr. Lauren Zeise)[hereinafter OMB vs. the Agencies] reprinted in Risk Assessment: Strengths and Limitations of Utilization for Policy Decisions, Hearing Before the Subcomm. on Environment of the House Comm. on Science, Space,and Technology, 102d Cong., 1st Sess. 53, 226 - 281 (1991).

231. *Id.*

232. OMB vs. the Agencies, *supra* note 230, at 15 (comments by Dr. Lauren Zeise).

options because one large nonconservative error can wipe out several smaller conservative errors; no one apparently knows the magnitude of any particular error. Improvements in risk assessments can be expected as science improves[233], but for the foreseeable future substantial knowledge and data gaps will remain. In the interim, the Agency has adopted some of the OMB recommendations.

b. The Agency Response

The Agency has recently reemphasized the requirement for EPA risk assessors to provide complete and balanced discussions of the reliability of risk characterization figures and the need to discuss all related uncertainties.[234] The 1992 Guidelines for Exposure Assessment also stress that risk assessors provide complete explanations for all inferences made and contain extensive guidance for dealing with data gaps and other uncertainties.[235] For example, when dealing with data gaps, risk assessors are told that conservative assumptions may be used, but if used, risk assessors are limited to expressing any resulting exposure or dose as an upper limit rather than a best estimate.[236] In the 1992 Guidelines for Exposure Assessment, in

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233. For a discussion of improvements in risk assessment science, *see* Elizabeth L. Anderson, *Scientific Developments in Risk Assessment: Legal Implications*, 14 Colum. J. Envtl. L. 411 (1989)

234. Habicht Memo, *supra* note 90, at 2-3.

235. *Supra* note 160, at 22,930.

236. *Id.* at 22,917.

apparent answer to an OMB critique, the Agency warns "obviously, the mathematical product of several conservative assumptions is more conservative than any single assumption alone. Ultimately, this could lead to unrealistically conservative bounding estimates."[237]

Elsewhere in the 1992 Guidelines for Exposure Assessment, EPA devotes an entire section to assessing and describing uncertainty.[238] The Guidelines provide inference options for three categories of uncertainty: (1) uncertainty regarding missing or incomplete information needed to fully define the exposure and dose (scenario uncertainty exposure); (2) uncertainty regarding some parameter which includes measurement errors, sampling errors, variability or errors from the use of generic or surrogate data (parameter uncertainty); and (3) uncertainty regarding gaps in scientific theory required to make predictions on the basis of causal inferences (model uncertainty).[239]

Risk assessors must discuss each type of uncertainty as part of the risk characterization. For scenario uncertainty, risk assessors should provide a discussion which allows "the reader to make an independent judgment about the validity of the conclusions reached by the assessor with any inferences, extrapola-

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237. *Id.* at n.26.

238. *Id.* at 22,925-29.

239. *Id.* at 22,926-28.

tions, and analogies used and the weight of evidence that led the assessor to particular conclusions."[240] For model uncertainty:

> At a minimum, the exposure assessor should describe in qualitative terms the rationale for selection of any conceptual and mathematical models. This discussion should address the status of these approaches and any plausible alternatives in terms of their acceptance by the scientific community, how well the model(s) represents the situation being assessed, e.g., high end estimate and to what extent verification and validation have been done.

Risk assessors must also provide risk assessments performed by other Federal agencies as well as any prior EPA risk assessments that have been done on the substance in question or other analogous substances.[241]

The Agency also addressed some of the OMB concerns regarding use of the most-exposed-individual ("MEI") and upper confidence limit ("UCL") to describe risk estimates. The Deputy Administrator directed risk assessors to use the standard descriptors of risk described in the 1992 Exposure Assessment Guidelines to promote comparability and consistency across programs at EPA.[242] The Agency policy is now that risk assessors must characterize risk using "high end" risk descriptors.[243] In contrast to UCL estimates which "purposely overestimate the exposure or dose in an actual population for the purpose of developing a statement that the 'risk is not greater than . . .'," high end estimates

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240. *Id.* at 22,927.

241. *Id.* at 22,930.

242. Habicht Memo, *supra* note 90, at 4-5.

243. *Id.* at 5.

are those found in the risk distribution above the 90th percentile of an actual (either measured or estimate) distribution.[244] Worst-case scenarios, "the combination of events and conditions such that, taken together, produce the highest conceivable risks, are now frowned upon as probabilities so low "that such combinations will not occur, in a particular, actual population."[245] EPA's policy is now to provide risk descriptors that always fall within the actual distribution. Since the hypothetical MEI is derived from the worst-case scenario, he should no longer appear in risk characterizations except perhaps in the occasional footnote.

In sum the Agency has focused on addressing concerns about conservatism in the risk characterization step. Risk assessors will provide less conservative estimates of risk along with expansive discussions of uncertainties and assumptions. No changes have yet appeared to address the reliance on animal studies or no-threshold models.

c. Risk Management Issues

Risk management critiques focus on the risk managers use of the risk estimate in the statutory context within which the risk manager must make his decision. Many, of the risk management critiques can be categorized as attempts to show that the benefit from setting a standard does not equal the harm or cost of the standard. Many of the arguments are powerful in themselves, but

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244. RAC Guidance, *supra* note 90, at 23-24.

245. *Id.* at 23.

are far more powerful when combined with the idea that the risk estimate itself is too conservative. Dr. Whipple's framework of assumptions that need to be true for conservatism to be protective in environmental risk assessment highlight the role of cost-benefit analysis in risk management.[246]

OMB has been critical of the costs of health and safety regulation in relation to the benefits provided and has estimated Federal health and safety regulations cost between $78 billion and $107 billion in 1988.[247] In a recent study, OMB examined current Federal risk management practices and found that cost-effectiveness for health and safety regulatory actions varied over more than eight orders of magnitude from about $100,000 to more than $5 trillion per premature death prevented.[248] Generally, OMB found that regulatory actions aimed at reducing safety hazards consistently cost below $10 million with many that have stayed below $1 million; in contrast health related regulations have consistently cost more per unit of risk reduction obtained.[249] OMB found that regulatory actions taken by EPA and the Health Standards Division of the Occupational Safety and

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246. *See supra* text accompanying note 55.

247. Office of Management and Budget, *Regulating Risk: The Cost Effectiveness of Federal Efforts To Reduce Health and Safety Risks* in Regulatory Program of the United States Government April 1, 1991 - March 31, 1992, Executive Office of the President 8 (1991) (citing Robert W. Hahn & John A. Hird, *The Costs and Benefits of Regulation: Review and Synthesis*, 8 Yale J. on Reg. 233 (1991)).

248. *Id.* at 10.

249. *Id.*

Health Administration to be the most expensive per unit of social benefit obtained and that the largest percentage of the most expensive regulatory actions were aimed at reducing "very small cancer risks."[250] OMB asserted that aggregate mortality risks could be substantially reduced at much less cost by shifting the Federal government's focus away from relatively small cancer risks to other risks and causes of injury.[251]

OMB has advanced another argument related to the cost of regulation known as "net health analysis" or "wealth equals health." Net health analysis is based on research that has investigated the relationship between income and health and has shown that mortality rates for higher income individuals is generally less than for lower income individuals.[252] The idea is based on the fact that all government expenditures are eventually borne by individuals and that all individuals are poorer in the sense that they will have less disposable income available as they pay for increasingly expensive health and safety regulations. To complete the argument one must assume that the lost disposable income would have been used in ways that on average would have reduced the mortality risks of individuals.[253] Several plausible scenarios support this assumption: in families with

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250. *Id.* at 11.

251. *Id.*

252. Ralph L. Keeney, *Mortality Risks Induced by Economic Expenditures*, 10 Risk Analysis 147 (1990).

253. *Id.* at 148.

more disposable income babies may receive more prenatal care; adults may undergo more physical exams, preventive mammographies and pap smears, people may purchase more safety equipment such as smoke detectors and optional items such as passenger side airbags on cars.[254] More disposable income may be spent on better education or moving to safer neighborhoods; a general increase in the standard of living in a society also leads to better and more diverse medical research establishment, increases in health clubs and a general social resilience to unforeseen problems which may threaten collective health.[255]

Professor Keeney applied a method to estimate the number of excess fatalities that are caused by the economic costs of government programs that decrease the disposable income of individuals; one example of his model using data from two previous studies for costs and fatalities showed that there is one induced fatality for every $7.25 million spent.[256] Although he warned that his calculations using his model were "illustrative only," others picked up on the powerful argument his analysis provides for choosing among health and safety government programs.

Judge Stephen F. Williams cited the work of Professor Keeney in a concurring opinion in *International Union, United Automobile, Aerospace and Agricultural Implement Workers of America v.*

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254. *Id.*

255. *Id.*

256. *Id.* at 155.

Occupational Safety and Health Administration to refute the proposition that a regulation based on a risk-benefit analysis is necessarily more protective of health and safety than a regulation based on a cost-benefit analysis.[257] The majority had ruled that OSHA had acted outside of its authority when it had attempted to require employers to use lockout devices on electrical equipment to protect employees from unexpected equipment starts.[258] Judge Williams wrote that larger incomes enable people to lead safer lives and that at some point incremental safety or health programs may actually cost more lives than they save. Judge Williams advocated determining a cost figure that could be used as a ceiling to determine when the implementation of a regulation might result in a net loss of life.[259]

OMB reportedly advocated the "wealth equals health" analysis to try to block review of a Labor Department proposal to expand OSHA regulations limiting workplace exposures to chemicals using a slightly higher figure, $7.5 million of regulatory expenses per fatality, than the $7.25 million found in Professor Keeney's paper.[260] Although OMB eventually allowed the proposals to be

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257. 938 F.2d 1310, 1326 (D.C. Cir. 1991).

258. *Id.*

259. *Id.*

260. Bob Davis & Albert R. Karr, *Bush to Require Regulators to Weigh Costs and Impact on Health, Mortality*, Wall St. J., Mar. 20, 1992, at A3.

reviewed, OMB announced it intended to apply the same analysis to other regulations proposed by federal agencies.[261]

VII. Judicial Response to Agency Reliance on Risk Methodologies

Although a constitutional parallel exists between rulemaking and statute making,[262] agencies must go further to survive judicial review. During judicial review of a law passed by Congress or a regulation created by an agency, a court will presume the existence of facts necessary to sustain a legislative or administrative rule.[263] However, while the inquiry ends at that point when a court reviews a law of Congress, the inquiry only begins for a regulation of an agency. The parallel ends because all agencies must comply with the Administrative Procedure Act (APA) which requires that all rulemaking be reasoned (not arbitrary and capricious) and based on an adequate administrative record after public notice and comment.[264] In particular environmental statutes, Congress has added additional requirements beyond those found in the APA.[265] The requirement to demonstrate reasoned

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261. *See Cost-Benefit Analysis—OMB 'Wealth Equals Health' Approach Here to Stay*, Environmental Policy Alert, May 13, 1992, at 41.

262. Bernard Schwartz, Administrative Law § 4.10 (3rd ed. 1991).

263. See Pacific States Box & Basket Co. v. White, 296 U.S. 176 (1935).

264. 5 U.S.C. §§ 553, 706. *See* Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 420 (1971).

265. *E.g.* 15 U.S.C. § 2605 (1988) (requiring Agency during rulemaking under TSCA to allow oral presentations and cross-examination of such witnesses); 15 U.S.C. § 2618 (1988) (requiring court must find the Agency rule supported by "substan-

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decisionmaking from an adequate administrative record forces the Agency to search for defensible explanatory models like risk assessment for the decisions the Agency makes when implementing its statutes.

The courts have ranged between two extremes when examining agency decisionmaking based on risk estimates. On the one hand, courts have been highly deferential to agency decisions based on the "frontiers of science" and have allowed agencies to make decisions with less than certain knowledge.[266] On the other hand, courts have closely scrutinized agency decisionmaking when the outcomes have been based on conservative risk estimates which impact upon other societal interests.[267] As previously noted, federal agencies need far less proof of causation to create regulations than individuals need to prove liability in tort.[268] Courts needed to develop the law to necessary to allow the agencies to regulate on the basis of risk of harm instead of proof of actual harm. One of the earliest cases to uphold an agency action on this basis was *Reserve Mining Co. v. EPA*.[269]

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265. (...continued)
tial evidence in the rulemaking record taken as a whole" when reviewing TSCA rulemaking); 42 U.S.C.A. § 7607(d) (West Supp. 1991) (establishing Agency requirement to maintain a comprehensive "air docket" as the administrative record for most rules created under the Clean Air Act).

266. *See* Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976).

267. *See* Gulf South Insulation v. U.S. Consumer Product Safety Commission, 701 F.2d 1137 (1983).

268. *See supra* text accompanying note 83.

269. 514 F.2d 492 (8th Cir. 1975) (en banc).

One of the issues in *Reserve Mining Co. v. EPA*, was whether Reserve Mining's discharge of tailings containing asbestos into Lake Superior violated the water quality regulations promulgated by the state of Minnesota as directed under the Clean Water Act.[270] The water quality regulations prohibited the discharge of wastes which cause offensive or harmful effects. Although at the time of the case asbestos had been proven to be a carcinogen when inhaled, the court found only weak and conflicting evidence for carcinogenicity when asbestos is ingested in drinking water and noted tremendous uncertainty over the likely amount of exposure from ingestion.[271] Nonetheless, the court enjoined Reserve Mining Co. from discharging effluent containing asbestos on the basis that the discharges "threatened harm" to the public; the Agency need not prove the discharges caused any harm.[272]

The analysis of the *Reserve Mining* court was cited with approval in *Ethyl Corporation v. EPA* which was tasked with reviewing the basis for the EPA's regulation of lead additives in gasoline.[273] At the time of that case, the Administrator of the Agency was permitted to control or prohibit the sale of fuel additives if he found any of the emission products of the fuel additive "will endanger the public health or welfare" after consideration of all relevant medical and scientific evidence

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270. *Id.* at 507.

271. *Id.* at 509-20.

272. *Id.* at 528.

273. 541 F.2d 1 (1976).

available to him.[274] Judge Skelly Wright agreed with the Administrator that "will endanger" meant "presents a significant risk of harm." and then went on to examine the circumstances necessary for such a finding.[275] The petitioners argued that because scientists disputed the amount of risk of harm from the levels of lead EPA sought to regulate, EPA should not be allowed promulgate the regulations. Judge Wright answered:

> Where a statute is precautionary in nature, the evidence is difficult to come by, uncertain, or conflicting because it is on the frontiers of science, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served. Of course, we are not suggesting that the Administrator has the power to act on hunches or wild guesses....We do hold that in such cases the Administrator may assess risks....The Administrator may apply his expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as "fact," and the like. We believe that a conclusion so drawn—a risk assessment—may, if rational, form the basis for health related regulations . . .[276]

The language used by Judge Wright is perhaps the most expansive authority for deference to Agency use of risk assessment procedures to support risk-based standards. Judge Wright also seems to have embraced the philosophy of Professor Page weighing in on the

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274. *Id.* at 11. The statutory provision has been amended to permit such regulation if "in the judgment of the Administrator any emission product of such fuel or fuel additive causes, or contributes to air pollution which may reasonably be anticipated to endanger public health or welfare." *See* 42 U.S.C.A. § 7545(c)(1)(A) (West Supp. 1992).

275. *Id.* at 13.

276. *Id.* at 28.

side of conservatism. At the very least, an agency would not be questioned under his approach for adopting conservative options.

Professor Sheila Jasanoff has proposed a three element model to show how courts initially reviewed agency reliance on scientific information like risk assessment estimates:

> 1) Agencies should be permitted to make regulatory decisions on the basis of imperfect knowledge (that is, suggestive rather than conclusive evidence);
> 2) Science policy determinations may be regarded as valid even if the scientific community doesn't universally regard it as such; and
> 3) When experts disagree about the validity or the interpretation of the relevant data, the administrative agency should have the authority to resolve the dispute consistently with its overall legal mandate.[277]

The Supreme Court has embellished this view stating that when an agency makes predictions within its area of special expertise at the frontiers of science, "a reviewing court must be generally at its most deferential."[278]

However, while courts will defer to agency decisions based on choices made from scientific models or interpretations of data, courts have also made it clear that these decisions must be "rational" as defined by the court and have held agencies to account for any gaps in reasoning. In a plurality decision now popularly known as the *Benzene* decision, the Supreme Court struck

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277. Jasanoff, *supra* note 133, at 50 (citing Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976); Reserve Mining Co. v. EPA, 514 F.2d 492 (8th Cir. 1975); Certified Color Manufacturers Assoc. v. Mathews, 543 F.2d 284 (D.C. Cir. 1976); EDF v. EPA, 598 F.2d 62 (D.C. Cir. 1978)).

278. Baltimore Gas & Electric Co. v. National Resources Defense Council, 462 U.S. 87 (1983)(reviewing the adoption by the Nuclear Regulatory Commission a series of generic rules to evaluate environmental impacts of a reactor's fuel cycle).

down an Occupational Safety and Health Administration (OSHA) standard that lowered the standard for occupational exposure to benzene from 10 parts per million (ppm) to 1 ppm.[279] The principal issue was whether OSHA could rely solely on studies showing that benzene had caused cancer at high exposures to set a standard limiting exposures to no greater that 1 ppm; OSHA had concluded that because benzene was a known carcinogen, no safe level of exposure could exist and had set the standard to the lowest level feasible.[280] OSHA's view was consistent with the no threshold theory of cancer causation; however, the Court was concerned about setting such a costly standard without any discussion of the size of health benefit gained.[281] OSHA had failed to make any findings that asserted the lower standard would be more protective than the old. During the course of the rulemaking, OSHA rejected industry testimony that used a dose-response curve for benzene derived from then current epidemiological evidence and a conservative extrapolation theory to show that the current exposure level (10 ppm) would cause at most two deaths out of a population of 30,000 workers every six

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279. Industrial Union Department v. American Petroleum Institute, 448 U.S. 607 (1980).

280. *Id.* at 634.

281. OSHA had estimated capital investments and first year operating costs would range from $453-471 million and annual operating costs of around $34 million to implement the new standard benefiting approximately 35,000 employees. *Id.* at 628-629.

years.[282] The Court noted that OSHA failed to discuss whether it was possible to make a rough estimate from existing epidemiological data and animal studies done at high exposure levels, or the significance of the risks attributable to those levels or whether it was possible to extrapolate from such estimates to derive a risk estimate for the lower exposures.[283] The Court stated, "Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as unsafe."

Although arguably the *Benzene* decision stands only for the proposition that OSHA failed to explain the model linking the risks from the high exposure data it had to the risks from the lower limits it sought to regulate, other courts have interpreted the Benzene decision to require OSHA to provide a numerical estimate of the actual risk posed by a substance at the level sought to be regulated.[284] In a recent case, *American Federation of Labor and Congress of Industrial Organizations v. OSHA*, the Eleventh Circuit Court of Appeals struck down OSHA standards for 428 toxic substances that OSHA promulgated in a single rulemaking.[285] OSHA again failed to demonstrate how each of the

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282. *Id.* at 654.

283. *Id.* at 632 n. 33.

284. *See* Public Citizen Health Research Group v. Tyson, 796 F.2d 1479 (D.C. Cir. 1986).

285. No. 89-7185, 1992 WL 135775 (11th Cir. Jul. 7, 1992).

substances posed a significant health risk at the level regulated; the court cited the *Benzene* decision in basing its decision on OSHA's failure to quantify risk.[286]

The lesson agencies like EPA have learned from the *Benzene* decision is that risk quantification is necessary to support risk-based standards. The *Benzene* decision has undoubtedly influenced EPA and other federal agencies to support risk-based standards using risk assessment methodologies. By obtaining data demonstrating the hazard, articulating a dose-response relationship that can be quantified to an unacceptable risk given the real world exposure level, an Agency can expect deference from a court during judicial review. While the *Benzene* decision did not speak to the amount of deference a court should give to the conservative options chosen by the Agency for a well designed risk assessment study, it does stand for the proposition that the court remains the final arbiter of whether an Agency explanation for any gaps in reasoning is sufficient. Both OSHA cases show that the courts will vacate regulations where an agency has stretched too far.

One case, however, has gone further in questioning agency reliance on risk assessment. In *Gulf South Insulation v. U.S. Consumer Product Safety Commission (CPSC)*, the Fifth Circuit Court of Appeals vacated a CPSC rule banning urea-formaldehyde foam insulation (UFFI) in residences and schools.[287] CPSC had

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286. *Id.* at *10.

287. 701 F.2d 1137 (1983).

based its rule in part on a cancer risk assessment which relied on a single animal bioassay study that showed that a lifetime cancer risk to persons living in homes insulated with UFFI would be from 0 to 37 or from 0 to 51 additional cancers per million person exposed.[288] Industry attacked the risk assessment in a number of ways reminiscent of the critiques made by OMB. First, industry disputed the data used in the exposure assessment arguing that the formaldehyde levels found in the test homes were not accurate indicators of the true exposure in an average UFFI home and second, industry argued the CPSC erred in relying exclusively on the single rat study ignoring epidemiological data that indicated formaldehyde is not a human carcinogen (the problem of the false negative again).[289] Industry also disputed the use of an upper confidence limit to arrive at the estimated risk, the use of high dose techniques to induce cancer in the animals tested and the assumptions incorporated into the computer program that the CPSC used to estimate risk.[290] The *Gulf South* court agreed with industry on the first two arguments and then in a footnote questioned one of the basic assumptions upon which risk assessment relies:

> Probably the most controversial assumption incorporated into Global 79 [the computer program used to estimate risk] is that the risk of cancer from formaldehyde is linear at low

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288. *Id.* at 1141-42.

289. *Id.* at 1143.

290. *Id.*

> doses—in other words there is no threshold below which formaldehyde poses no risk of cancer.[291]

The court vacated the rule and closed by stating "that the selection of procedures [used to regulate products] is too important to be based on unexplored theories and desires for administrative convenience."[292]

Although the *Gulf South* case is the most extreme example of intrusive judicial review of agency reliance on risk assessment methodologies, the case nonetheless illustrates the ease with which a court may find the uncertainties inherent in the risk assessment process fatal to an agency rulemaking. Recent guidance to EPA risk assessors and risk managers requires openness in discussing uncertainties, assumptions and choice of inference options.[293] At some point, however, such openness may invite intrusive judicial review as in *Gulf South*. When all the conflicting studies are discussed, uncertainties considered and inference options chosen, will an Agency decision be arbitrary and capricious or will it pass as reasoned decision making? Will judges give the Agency deference on the interpretation of animal bioassays or stack up unexplained "default assumptions" to find the evidence so unreliable that a rule must be vacated?[294]

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291. *Id.* at 1147.

292. *Id.* at 1150.

293. *See* Habicht Memo, *supra* note 90.

294. *But see* Latin, *Good Science*, *supra* note 58, at 130 (criticizing the *Gulf South* court's approach as unwarranted because of the state of science and the needs of administrative law.)

The risk management portion of the process is also subject to judicial review and has not received the deference given to science-based determinations like risk assessment. The treatment of risk management is necessarily more dependent upon the requirements of the particular statute being examined. In *Corrosion Proof Fittings v. EPA*, the court vacated a rule promulgated under TSCA prohibiting the future manufacture, importation, processing and distribution of asbestos in almost all products.[295] In addition to rulemaking defects,[296] the court found the rule not supported by substantial evidence in the rulemaking record.[297] While the court deferred to the Agency's determination of the health risk from asbestos, the found that EPA had failed to consider the risk management factors required by TSCA.[298]

The court began its analysis by finding that Congress did not intend TSCA to be zero-risk statute; EPA had to consider alternatives to a ban of asbestos products, the costs of any proposed actions, and, generally, to carry out the intent of TSCA in a reasonable and prudent manner after considering the environ-

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295. 947 F.2d 1201 (5th Cir. 1991).

296. The court found that EPA had failed to provide public notice that it intended to rely upon "analogous exposure data" to calculate the expected benefits of some of the product bans. *Id.* at 1212. EPA used the data to increase the benefits of the asbestos rule from 120 lives saved to 168 lives save. *Id.*

297. *Id.* at 1213.

298. *Id.* at 1229.

mental, economic, and social impact of any action.[299] In risk assessment/risk management parlance, once asbestos was shown to present a risk to human health, TSCA requires the Agency to balance the risk against the benefits provided by the substance. The court found that EPA's failure to consider each alternative mentioned in TSCA in the rulemaking record constituted "a failure to meet its burden of showing that its actions not only reduce the risk but do so in the Congressionally-mandated *least burdensome* fashion [emphasis in original]."[300]

The court also found fault with EPA's methodology for calculations comparing the risks and benefits of its asbestos ban. EPA had run estimates of lives saved versus costs over a thirteen year period and considered lives saved after thirteen years to be "unquantified benefits." The court noted that the thirteen year period was so short as to make "the unquantified period so unreasonably large that any EPA reliance upon it must be displaced."[301]

The court questioned why EPA had banned products for which substitutes were available which may increase risks to human health. Although TSCA does not explicitly require EPA to examine the risk posed by substitutes before banning a substance, the court found that such a determination is necessary to accurately

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299. *Id.* at 1215.

300. *Id.* at 1217.

301. *Id.* at 1291.

figure the benefits to be gained by banning a substance.[302] The court agrees with Dr. Whipple; conservatism does not make sense if the result is the creation of new risks.[303] The court noted that two substitutes for asbestos products, non-asbestos brakes and polyvinyl chloride ("PVC") pipe have risks that are plausible and known and stated that EPA must consider not only the probable costs of continued use of the product it is considering, but also the harm that would follow from its regulation and increased use of an alternate, harmful product.[304] "In short, a death is a death, whether occasioned by asbestos, or by a toxic substitute product, and the EPA's decision not to evaluate the toxicity of known carcinogenic substitutes is not a reasonable action under TSCA."[305]

Finally, the court examined the cost of the EPA's asbestos ban in terms of the estimated lives the regulation would save over the next thirteen years in the light most favorable to the agency's decision: EPA estimated its ban of asbestos pipe would save three lives at a cost of $128-227 million ($43-76 million per life per life saved), its ban of asbestos shingles would save 0.32 lives at a cost of $23-34 million ($72-106 million per life saved); its ban of asbestos coatings would save 3.33 lives at a cost of $46-181 million ($14-54 million per life saved); and its

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302. *Id.* at 1220-21.

303. *See supra* text accompanying note 55.

304. 947 F.2d at 1221-22 n. 21.

305. *Id.* at 1221.

ban of asbestos paper products will save .60 lives at a cost of $4-5 million ($7-9 million per life saved).[306] The size of the cost in relation to the lives saved caused the court to conclude that EPA had basically ignored the cost side of the TSCA analysis. "The EPA would have this court believe that Congress, when it enacted its requirement that EPA consider the economic impacts of its regulation, thought that spending $200-300 million to save approximately seven lives (approximately $30-40 million per life) over thirteen years is reasonable.[307] Here, again, the court is asking the Agency to examine whether an assumption on which conservatism relies is true. At some point costs become so high that the balance of social costs must tip in favor of less regulation.

VIII. Conclusion

What is the Risk Commission likely to report to Congress in 1994 after investigating the risk assessment and risk management practices of the federal agencies? The Commission may develop an attitude toward risk assessment similar to the sentiment expressed by Winston Churchill. The British Prime Minister claimed that democracy is the worst form of government—except for all the others.[308] Risk assessment for all its uncertainties is

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306. *Id.* at 1222.

307. *Id.* at. 1223.

308. *See* Speech by Sir Winston Churchill, House of Commons, Nov. 11, 1947 in The Oxford Dictionary of Quotations 150 (3rd. Ed. 1980).

simply the best tool available for predicting the likely effect of potentially hazardous substances.

A review of the environmental statutes and cases has revealed that risk assessment is necessary to quantify risks for all statutes employing risk-based standards; EPA uses risk assessment to make other regulatory decisions as well. However, when risk-based standards must be set, the Agency has had difficulty promulgating regulations in reasonable time frames. Congress has recognized this problem in the CAAA of 1990 by using technology-based standards to address risks from hazardous air pollutants and reserving risk-based standards for residual risk.

A review of the nature of environmental risk showed the genesis of the conservative bias that has developed in risk assessment methodologies. EPA risk assessors have consistently chosen conservative risk assessment components to address uncertainties about the true risk from hazardous substances. However, it was seen that the most conservative options for dealing with an environmental risk do not necessarily achieve the most protective result. Conservatism is warranted only to the extent the difference in social costs between the error of deciding toxic substances are not toxic and the error of deciding a nontoxic substance is toxic is great; the cost of regulating the toxic substance does not preclude applying resources to ameliorate greater risks; or the elimination of the risk posed by toxic substance does not increase the overall risk from an increase in the use of substances or activities posing greater risks.

Examination of the risk assessment - risk management framework has shown that EPA has been successful in separating the risk assessment process from those engaged in risk management, but at an initial cost of hiding important information about the assumptions made by the risk assessment community.

The Risk Commission will be able to report that EPA has come to realize the danger of preferring the most conservative options in the risk assessment process as well as the danger of hiding behind single point estimates of risk. The Agency's new policy of providing risk managers with a complete discussion of all assumptions and uncertainties as part of the risk characterization will enable risk managers to create better standards and make better decisions as well as inform the public of the true range of risk presented from a particular substance or activity. The Agency's policy of openness should encourage debate about how risk estimates should be formed and increase public confidence in the regulatory process. Although, this policy of openness carries with it the risk of intrusive judicial review, well conducted studies with careful explanations for all assumptions used to bridge data and knowledge gaps should go far toward meeting the Agency's burden of proof.

A review of risk management issues has revealed the power of cost-based arguments which attack the assumptions needed to support conservatism when regulating on the basis of risk. The Risk Commission should carefully examine the underpinnings of the "wealth equals health" argument, because, if validated, Congress

would have a potent tool to limit regulatory excess by providing a dollar "ceiling" by which to judge any new health or safety program.

Finally, the Risk Commission should remind Congress that courts and agencies are bound by the language used in the statutes. For balancing standards, courts and agencies can consider the full impact of regulations have wide latitude to consider the full panoply of risk management arguments. Under harm-based statutes that do not permit any risk the Agency and the courts have no choice, but to impose strict standards that may only appear protective. Language that does not allow the Agency sufficient discretion to regulate at levels of reasonable risk can also result in "paralysis by analysis." Fragmented statutes with widely different standards for risk cannot allow for effective comparison of regulatory programs on the basis of relative risk.

Appendix

Hazard Identification

Epidemiologic Data

- What relative weights should be given to studies with differing results? For example, should positive results outweigh negative results if the studies that yield them are comparable? Should a study be weighted in accord with its statistical power?
- What relative weights should be given to results of different types of epidemiologic studies? For example, should the findings of a prospective study supersede those of a case-control study, or those of a case-control study those of an ecologic study?
- What statistical significance should be required for results to be considered positive?
- Does a study have special characteristics (such as the questionable appropriateness of the control group) that lead one to question the validity of its results?
- What is the significance of a positive finding in a study in which the route of exposure is different from that of a population at potential risk?
- Should evidence on different types of responses be weighted or combined (e.g., data on different tumor sites and data on benign versus malignant tumors)?

Animal Bioassay Data

- What degree of confirmation of positive results should be necessary? Is a positive result from a single animal study sufficient, or should positive results from two or more animal studies be required? Should negative results be disregarded or given less weight?
- Should a study be weighted according to its quality and statistical power?
- How should evidence of different metabolic pathways or vastly different metabolic rates between animals and humans be factored into a risk assessment?
- How should the occurrence of rare tumors be treated? Should the appearance of rare tumors in a treated group be considered evidence of carcinogenicity even if the finding is not statistically significant?
- How should experimental-animal data be used when the exposure routes in experimental animals and humans are different?
- Should a dose-related increase in tumors be discounted when the tumors in question have high or extremely variable spontaneous rates?
- What statistical significance should be required for results to be considered positive?
- Does an experiment have special characteristics (e.g., the presence of carcinogenic contaminants in the test substance) that lead one to question the validity of its results?

- How should findings of tissue damage or other toxic effects be used in the interpretation of tumor data? Should evidence that tumors may have resulted from these effects be taken to mean that they would not be expected to occur at lower doses?
- Should benign and malignant lesions be counted equally?
- Into what categories should tumors be grouped for statistical purposes?
- Should only increases in the numbers of tumors be considered, or should a decrease in the latent period for tumor occurrence also be used as evidence of carcinogenicity?

Short-Term Test Data

- How much weight should be placed on the results of various short-term tests?
- What degree of confidence do short-term tests add to the results of animal bioassay in the evaluation of carcinogenic risks for humans?
- Should in vitro transformation tests be accorded more weight than bacterial mutagenicity tests in seeking evidence of a possible carcinogenic effect?
- What statistical significance should be required for results to be considered positive?
- How should different results be weighted? Should positive results be accorded greater weigh than negative results?

Structural Similarity to Known Carcinogens

- What additional weight does structural similarity add to the results of animal bioassay in the evaluation of carcinogenic risks for humans?

General

- What is the overall weight of the evidence of carcinogenicity? (This determination must include a judgment of the **quality** of the data presented in the preceding sections.)

Dose-Response Assessment

Epidemiologic Data

- What dose-response models should be used to extrapolate from observed doses to relevant doses?
- Should dose-response relations be extrapolated according to best estimates or according to upper confidence limits?
- How should risk estimates be adjusted to account for a comparatively short follow-up period in an epidemiologic study?
- For what range of health effects should responses be tabulated? For example, should risk estimates be made only for specific types of cancer that are unequivocally related to exposure, or should they apply to all types of cancers?
- How should exposures to other carcinogens, such as cigarette smoke, be taken into consideration?

- How should one deal with different temporal exposure patterns in the study population in the study population and in the population for which risk estimates are required? For example, should one assume that lifetime risk is only a function of total dose, irrespective of whether the dose was received in early childhood or in old age? Should recent doses be weighted less than earlier doses?
- How should physiologic characteristics be factored into the dose-response relation? For example, is there something about the study group that distinguishes its response from that of the general population?

Animal-Bioassay Data

- What mathematical models should be used to extrapolate from experimental doses to human exposures?
- Should dose response relations be extrapolated according to best estimates or according to upper confidence limits? If the latter, what confidence limits should be used?
- What factor should be used for interspecies conversion of dose from animals to humans?
- How should information on comparative metabolic processes and rates in experimental animals and humans be used?
- If data are available on more than one nonhuman species or genetic strain, how should they be used? Should only data on the most sensitive species or strain be used to derive a dose response function, or should the data be combined? If the data on different species and strains are to be combined, how should this be accomplished?
- How should data on different types of tumors in a single study be combined? Should the assessment be based on the tumor type that was affected the most (in some sense) by the exposure? Should data on all tumor types that exhibit a statistically significant dose-related increase be used? If so, how? What interpretation should be given to statistically significant **decreases** in tumor incidence at specific sites?

Exposure Assessment[1]

- How should one extrapolate exposure measurements from a small segment of a population to the entire population?
- How should one predict dispersion of air pollutants into the atmosphere due to convection, wind currents, etc., or predict seepage rates of toxic chemicals into soils and groundwater?

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1. Current methods and approaches to exposure assessment appear to be medium- or route-specific. In contrast with hazard identification and dose response assessment, exposure assessment has very few components that could be applicable to all media.

- How should dietary habits and other variations in lifestyle, hobbies, and other human activity patterns be taken into account?
- Should point estimates or a distribution be used?
- How should differences in timing, duration, and age at first exposure be estimated?
- What is the proper unit of dose?
- How should one estimate the size and nature of the populations likely to be exposed?
- How should exposures of special risk groups, such as pregnant women and young children, be estimated?

Risk Characterization

- What are the statistical uncertainties in estimating the extent of health effects? How are these uncertainties to be computed and presented?
- What are the biologic uncertainties in estimating the extent of health effects? What is their origin? How will they be estimated? What effect do they have on quantitative estimates? How will the uncertainties be described to agency decisionmakers?
- What dose-response assessments and exposure assessment should be used?
- Which population groups should be the primary targets for protection, and which provide the most meaningful expression of health risk.

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